State of California
AIR RESOURCES BOARD

Staff Report: Initial Statement of Reasons for Proposed Rulemaking

Public Hearing to Consider the Adoption of a Regulatory Amendment Identifying Ethylene Oxide as a Toxic Air Contaminant

Agenda Item No.: 87-__
Scheduled for Consideration: November 12, 1987
Release Date: September 25, 1987

EXECUTIVE SUMMARY

INTRODUCTION AND RECOMMENDATION

Health and Safety Code Section 39655 defines a toxic air contaminant as an air pollutant which the Air Resources Board or the Department of Food and Agriculture finds "may cause or contribute to an increase in mortality or an increase in serious illness, or which may pose a present or potential hazard to human health". The staffs of the Air Resources Board (ARB) and the Department of Health Services (DHS) have reviewed the available scientific evidence on the presence of ethylene oxide in the atmosphere of California and its potential adverse effect on public health. Based on the finding of carcinogenicity and the results of the risk assessment, the DHS staff finds that ethylene oxide meets the definition of a toxic air contaminant. Therefore, the staff of the Air Resources Board recommends that ethylene oxide be identified by the Board as a toxic air contaminant. In making this recommendation, the ARB and DHS staffs found that there is not sufficient available scientific evidence at this time to support the identification of an exposure level below which carcinogenic effects would not have some probability of occurring and recommend that ethylene oxide be treated as having no identified threshold.

The Scientific Review Panel (SRP), established by Health and Safety Code Section 39670, reviewed the report in accordance with Health and Safety Code Section 39661, and found the report to be without serious deficiency. The findings of the SRP are attached at the end of the Executive Summary.

Ethylene oxide was chosen for evaluation because: it has been identified by the International Agency for Research on Cancer (IARC) as an animal carcinogen and a probable human carcinogen; it is emitted from several sources in the state; and it will not break down at a rate that would significantly reduce the resulting public exposure.

SOURCES OF ETHYLENE OXIDE

In 1985, almost 3 million tons of ethylene oxide were produced in the United States. Most of this is for domestic use. Less than one percent of the ethylene oxide used in this country is imported and approximately one percent of production is exported. Production is expected to increase at a rate of approximately six percent per year for the next several years. The major uses of ethylene oxide are for the production of chemicals and for sterilization. Chemicals that are produced using ethylene oxide include surfactants, ethylene glycol, glycol ethers and ethanolamines. Its use as a sterilizing agent is mainly for medical and food products. Although only 0.5 percent of the total U.S. usage is as a sterilizing agent, this use accounts for over 90 percent of the identified ethylene oxide emissions in California.

The major identified source categories of ethylene oxide emissions in California are (in decreasing order of emission quantities):

1) sterilization at commercial facilities and hospitals;
2) fumigation of foods and spices;
3) surfactant manufacturing facilities; and
4) ethylene oxide distribution facilities.

Combustion of hydrocarbons may also be a significant source of ethylene oxide emissions, but not enough information is available to either determine if this could be the case, or to quantify this source of emissions.

EXPOSURE TO ETHYLENE OXIDE

In the atmosphere, ethylene oxide (EtO) is relatively stable to decomposition by gas phase processes, with an estimated lifetime* of 200 days or longer.** Its actual lifetime may be shorter due to processes such as adsorption onto particles or reactions with acid fog. Although the rates for these processes are difficult to quantify, the lifetime of ethylene oxide in the atmosphere is still expected to be on the order of at least several days. Results from dispersion modeling of emissions from all known sources within an area of Los Angeles County indicate that nearly seven million people were exposed to an estimated population-weighted annual average concentration*** of about 50 parts per trillion (ppt) (0.09 ug/m^3) of ethylene oxide in 1985. The maximum annual average concentration to which people were exposed was estimated to be 20,000 ppt (36 ug/m^3), near a large commercial emission source. Ambient air concentrations under worst-case meteorological conditions from large emission sources could range as high as four parts per million (7200 ug/m^3), on an hourly basis. Populations exposed to such concentrations cannot be calculated, but are expected to be very small. Modeling was

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* Atmospheric lifetime is defined as the time required for a given amount of compound to decrease 1/e (0.368) of its original value at the initial time.

** This estimate is based on an assumed hydroxyl radical concentration of one million molecules per cubic centimeter.

*** The population-weighted annual average concentration is defined as the exposure level to which the average person in an area is exposed over the course of a year, in excess of any background level.

used to estimate ambient concentrations and exposure because monitoring techniques are currently not sensitive enough to measure the concentrations to which the majority of people are probably exposed.

As a registered economic poison, ethylene oxide is regulated by the California Department of Food and Agriculture in its use as a sterilizing or fumigating agent. Therefore, although this report includes a discussion of overall ethylene oxide exposure, emphasis has been placed on exposure from distribution and from the manufacturing of surfactants, relatively minor sources which would be subject to regulation by the Air Resources Board. From one such source, a distribution facility in Los Angeles County, it is estimated that in 1985, about a quarter of a million people living in an area of about 25 square miles near downtown Los Angeles, were exposed to an annual average ethylene oxide concentration of five ppt (0.009 ug/m^3) or greater. Emissions from that same facility are believed to have resulted in 13,000 people being exposed to an annual average ethylene oxide concentration of about 40 ppt (0.07 ug/m^3) or greater.

Limited data indicate that smoking and ingestion may represent significant exposure routes.

HEALTH EFFECTS OF ETHYLENE OXIDE

The health effects of ethylene oxide have been reviewed and evaluated to determine whether ethylene oxide meets the definition of a toxic air contaminant as defined by California Health and Safety Code Section 39655. Inhaled ethylene oxide is rapidly distributed throughout the body. Acute and chronic exposure leads to respiratory tract irritation and central nervous system depression, as well as other pathologic changes. At high doses ethylene oxide can induce dominant lethal mutations and cause embryotoxicity in rodents. One epidemiologic study suggested an increase in spontaneous abortions due to ethylene oxide exposure. At current ambient levels of ethylene oxide estimated in this report (up to four parts per million or 7,200 ug/m^3, on an hourly basis), however, no acute or noncarcinogenic chronic effects are expected.

Ethylene oxide, presumably due to its ability to alkylate DNA, causes gene mutations in both prokaryotic and eukaryotic cells and leads to sister chromatid exchanges and chromosomal damage, including the formation of aberrations and micronuclei. Several types of tumors have been induced in rats by ethylene oxide. Administration of ethylene oxide by gavage induced tumors of the forestomach, i.e., at the site of application. Inhalational exposure led to increases in a variety of tumors. The strongest dose-dependent reponse was seen for peritoneal mesotheliomas in males and for mononuclear cell leukemias in females. There was also an increase in brain tumors, which are rarely seen in control animals. Epidemiologic studies of people occupationally exposed to ethylene oxide suggest that this exposure leads to increased incidences of stomach cancer and leukemia.

The International Agency for Research on Cancer (IARC) concluded that there is sufficient evidence for the carcinogenicity of ethylene oxide in animals; in humans, the evidence for carcinogenicity is limited. Overall, based on both the animal and human data, IARC considers that ethylene oxide is probably carcinogenic in people. DHS staff concurs with these conclusions. In addition, DHS staff has found no evidence of a threshold level for carcinogenicity of ethylene oxide.

RISK DUE TO ATMOSPHERIC ETHYLENE OXIDE

The DHS staff recommends that the range of risk for ambient exposure to ethylene oxide be based on the maximum likelihood estimate and upper 95% confidence limit predicted from fitting the multistage model to the animal data. The range of estimated excess lifetime cancer risks from 24-hour-per-day exposure for a lifetime to average ambient airborne concentrations, estimated to be 0.09 ug/m^3 (50 ppt), is 6 to 8 cases per million persons exposed. These values were also obtained by EPA in its Health Assessment Document for Ethylene Oxide using the same data. When the risk model is applied to the human epidemiologic data to predict excess cancers, the predictions are compatible with what has actually been observed; that is, the DHS risk assessment based on animal data is compatible with the human epidemiologic evidence. Exposure to the ambient value of 0.09 ug/m^3 (50 ppt), estimated by the Air Resources Board for an area in Los Angeles County, could result in up to 55 excess lifetime cancers (Upper 95% Confidence Limit) among the 7 million residents of that area. Individuals exposed to the maximum annual average concentration of 20,000 ppt (36 ug/m^3) for a lifetime would have a risk of developing cancer equal to one case per 330 people exposed.

Several other models proposed for cancer risk estimation by various investigators yielded an upper limit range of 52 to 417 excess lifetime cancers for 7 million people exposed to 0.09 ug/m^3 (50 ppt).

Based on the findings of carcinogenicity and the results of the risk assessment, DHS staff finds that ambient ethylene oxide is an air pollutant which may cause or contribute to an increase in mortality or an increase in serious illness, or which may pose a present or potential hazard to human health.

ALTERNATIVES

Government Code Section 11346.14 requires agencies to describe alternatives to the regulation considered by the agency and the agency's reasons for rejecting those alternatives. The only alternative to identifying ethylene oxide as a toxic air contaminant is to not identify it. ARB staff is not recommending this alternative because ARB staff believes that ethylene oxide meets the statutory definition of a toxic air contaminant. There are no alternatives considered by the ARB staff which would be more effective in carrying out the purpose for which the regulation is proposed or would be as effective and less burdensome to affected private persons than the proposed regulations.

SUMMARY OF ENVIRONMENTAL IMPACTS OF THE IDENTIFICATION OF ETHYLENE OXIDE AS A TOXIC AIR CONTAMINANT

The identification of ethylene oxide as a toxic air contaminant is not in itself expected to result in any environmental effects. The identification of ethylene oxide as a toxic air contaminant by the Board may result in the Board and air pollution control districts adopting toxic control measures in accordance with the provisions of state law (Health and Safety Code Sections 39665 and 39666). Any such toxic control measures would result in reduced emissions of ethylene oxide to the atmosphere, resulting in reduced ambient concentrations, concurrently reducing the health risk due to ethylene oxide exposure. Therefore, the identification of ethylene oxide as a toxic air contaminant may ultimately result in environmental benefits. Environmental impacts identified with respect to specific control measures will be included in the consideration of such control measures pursuant to Health and Safety Code Sections 39665 and 39666.

Amend Titles 17 and 26, California Administrative Code, Section 93000 to read as follows:

93000. Substances Identified As Toxic Air Contaminants. Each substance identified in this section has been determined by the state board to be a toxic air contaminant as defined in Health and Safety Code Section 39655. If the state board has found there to be a threshold exposure level below which no significant adverse health effects are anticipated from exposure to the identified substance, that level is specified as the threshold determination. If the board has found there to be no threshold exposure level below which no significant adverse health effects are anticipated from exposure to the identified substance, a determination of "no threshold" is specified. If the board has found that there is not sufficient available scientific evidence to support the identification of a threshold exposure level, the "Threshold" column specifies "None identified."

Substance	Threshold Determination
Benzene (C_6H_6)	None identified
Ethylene Dibromide ($BrCH_2CH_2Br$; 1,2-dibromoethane)	None identified
Ethylene Dichloride ($ClCH_2CH_2Cl$; 1,2-dichloroethane)	None identified
Hexavalent Chromium (Cr(VI))	None identified
Asbestos [asbestiform varieties of serpentine (chrysotile) riebeckite (crocidolite) cummingtonite-grunerite (amosite), tremolite, actinolite, and anthophyllite]	None identified
Dibenzo-p-dioxins and Dibenzofurans chlorinated in the 2,3,7 and 8 positions and containing 4,5,6 or 7 chlorine atoms	None identified
Cadmium (metallic cadmium and cadmium compounds)*	None identified
Carbon Tetrachloride* (CCl_4; tetrachloromethane)	None identified
Ethylene Oxide (1,2-epoxyethane)	None identified

NOTE: Authority cited: Sections 39600, 39601 and 39662, Health and Safety Code. Reference: Sections 39650, 39660, 39661 and 39662, Health and Safety Code.

*Note: Compounds identified by an asterisk have been identified as toxic air contaminants by the Air Resources Board but not yet approved by the Office of Administrative Law.

Report of the Scientific Review Panel on
THE REPORT ON ETHYLENE OXIDE
As adopted at the Panel's July 7, 1987 Meeting

In accordance with the provisions of Health and Safety Code Section 39661, the Scientific Review Panel (SRP) has reviewed the reports of the staffs of the APB and DHS on the public exposure and biologic and health effects of ethylene oxide, and the public comments on these reports. Based on this review, the SPP finds that the reports are without serious deficiencies and further finds that:

1. Ethylene oxide has been identified as an animal carcinogen and should be regarded as a potential human carcinogen.

2. Ethylene oxide is emitted into the air by a variety of stationary sources in California. Dispersion modeling of emissions from all known sources within an area of Los Angeles County indicates that nearly 7 million people were exposed to an estimated population-weighted annual mean concentration of 50 parts per trillion (ppt) (0.09 ug/m^3) of ethylene oxide in 1985. The maximum annual average concentration to which people were exposed was estimated to be 20,000 ppt (36 ug/m^3) near a large commercial emission source.

3. Based solely on its gas-phase reactivity, ethylene oxide has an atmospheric lifetime of approximately 200 days. Although possible reaction in solution or on surfaces could shorten this lifetime, based on available scientific evidence, ethylene oxide would still have an atmospheric lifetime of days to weeks.

4. Adverse health effects other than cancer are not known to occur at predicted concentrations of ethylene oxide in ambient outdoor air.

5. Based on available scientific information, an ethylene oxide exposure level below which carcinogenic effects are not expected to occur cannot be identified.

6. Based on an interpretation of available scientific evidence by DHS staff, the range of lifetime excess cancer risk from exposure to 0.56 ppb (1 ug/m^3) of atmospheric ethylene oxide based on the best animal estimate of risk and the upper 95% confidence limit is estimated to be 61 to 88 cases per million people exposed. These upper bound excess lifetime risks are health-protective estimates; the actual risk is likely to be below these values.

For these reasons, we agree with the ARB staff recommendation to its Board that ethylene oxide be listed by the ARB as a toxic air contaminant.

I certify that the above is a true and correct
copy of the findings adopted by the Scientific
Review Panel on July 7, 1987.

Dr. Thomas M. Mack, Acting Chairman
Scientific Review Panel

ERRATUM SHEET

TECHNICAL SUPPORT DOCUMENT
REPORT TO THE AIR RESOURCES BOARD ON ETHYLENE OXIDE

This report was considered by the California Air Resources Board on November 12, 1987. There is an error on page I-13 of Part A of the report. Table I-13, "POSSIBLE EXPOSURE TO ETHYLENE OXIDE THROUGH OTHER MEDIA", states that the exposure through ambient air exposure at 50 ppt concentration is .02 micrograms per day. This should be 2 micrograms per day.

The exposure through ambient air was calculated through an equation on page E-1 of Appendix E under the heading, "AMBIENT AIR". This equation consists of the 50 ppt concentration and various conversion factors, yielding an exposure. All numbers in the calculation are correct except for the result, which should be 2 micrograms per day, not 0.02 micrograms per day as stated.

State of California
AIR RESOURCES BOARD

TECHNICAL SUPPORT DOCUMENT

PUBLIC HEARING TO CONSIDER THE ADOPTION OF A REGULATORY AMENDMENT IDENTIFYING ETHYLENE OXIDE AS A TOXIC AIR CONTAMINANT

Agenda Item No: 87-__
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CONTENTS OF REPORT TO THE AIR RESOURCES BOARD ON ETHYLENE OXIDE

OVERVIEW AND RECOMMENDATION

I. SUMMARY

The staffs of the Air Resources Board (ARB) and Department of Health Services (DHS) collected, assessed and integrated the available scientific evidence on the presence of ethylene oxide in the atmosphere of California and its potential adverse effects on public health. This is a summary of the information presented in the resulting report.

State law defines a toxic air contaminant as an air pollutant which the Air Resources Board or the Department of Food and Agriculture finds "may cause or contribute to an increase in mortality or an increase in serious illness, or which may pose a present or potential hazard to human health". Based on the Department of Health Services staff's conclusion that ethylene oxide meets this definition, the staff of the Air Resources Board recommends that ethylene oxide be identified by the Board as a toxic air contaminant. In making this recommendation, the ARB and DHS staffs found that insufficient scientific evidence is available to support the identification of an exposure level below which carcinogenic effects would not have some probability of occurring and recommend that ethylene oxide be treated as having no identified threshold.

Ethylene oxide was chosen for evaluation for the following reasons: (1) the United States Environmental Protection Agency (EPA) classified ethylene oxide in Group B1, meaning that ethylene oxide should be considered as probably carcinogenic in humans; (2) the International Agency for Research on Cancer (IARC) concluded, based on both animal and human data, that ethylene oxide is probably carcinogenic in humans; (3)

ethylene oxide is emitted from many sources throughout the state; and (4) experimental and theoretical studies establish that ethylene oxide will not break down in the atmosphere at a rate that would significantly reduce the resulting public exposure.

Most of the ethylene oxide emitted in California is emitted from sterilization of medical devices and health care products by medical supply companies and hospitals. Additional ethylene oxide emissions are associated with fumigation of agricultural products such as spices, surfactant production, and distribution of tanks containing ethylene oxide.

The only gas-phase atmospheric removal process which is expected to be significant for ethylene oxide is reaction with the hydroxyl radical. Measurements of this reaction rate constant lead to the conclusion that ethylene oxide has an atmospheric lifetime* of 200 days or longer.

Ethylene oxide is also removed from the atmosphere through physical processes, such as rain washout and interaction with acid fog and acid rain. Because ethylene oxide is very volatile, rain is not believed to be very effective at washing it out. Furthermore, acid fog and acid rain conditions occur only a small percentage of the time in California. However, atmospheric lifetime under such conditions may be significantly shorter than 200 days.

General population exposures to atmospheric ethylene oxide were estimated by modeling the emissions of ethylene oxide from all known sources in a portion of Los Angeles County for 1985. A modeling approach

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* Atmospheric lifetime is defined as the time required for a given amount of a compound to decrease 1/e (0.368) of its original value at the initial time.

was used because the highest levels of ethylene oxide in the ambient air were anticipated to be lower than the current detection limits for ambient monitoring analysis, but possibly within the range of risks which could be of concern. Using this modeling approach, the population-weighted annual average concentration was estimated. This concentration defines the exposure level to which the average person in an area is exposed over the course of a year, in excess of any background level. The DHS upper-limit risk estimate was multiplied by this concentration, and then applied to the population in the exposed area to determine the number of cancer cases expected from exposure to the emission sources.

ARB staff estimated that in 1985, nearly seven million people in the Los Angeles County study area were exposed to a population-weighted annual average ethylene oxide concentration of about 50 ppt (parts per trillion) or about 0.09 ug/m^3 (micrograms per cubic meter). Rough estimates were also made for other urban areas of California. Urban areas with only hospital sterilizer emissions as sources of ethylene oxide are estimated to have ethylene oxide concentrations of about 9 ppt (0.016 ug/m^3).

Estimated concentrations of ethylene oxide in the atmosphere are much lower than those which are associated with non-cancer chronic adverse health effects or acute health effects observed in occupational settings or in animal experiments. Because of this, and because ethylene oxide is thought to exhibit a threshold effect for non-cancer health effects, adverse health effects other than cancer are not expected to occur due to inhalation of ethylene oxide at current or anticipated atmospheric concentrations.

DHS staff performed a cancer risk assessment based upon the female rat mononuclear cell leukemia data from the Snellings et al. (1984) study, using the multistage model. These data were used because they represent the most sensitive sex, site, and species for carcinogenic effects. The cancer risk at ambient levels was estimated by extrapolating four orders of magnitude from these data, using the best fit of the linearized multistage model. This model provides a health-protective risk estimate because it is linear at low doses. In addition, DHS staff fit several other models to the data for comparison.

For the purpose of assessing risks due to ambient ethylene oxide, exposure estimates were based on the air modeling data for the Los Angeles area developed by ARB staff. Assuming that seven million people are exposed to 0.09 ug/m^3 (50 ppt) ethylene oxide, the multistage model predicts an upper 95% confidence limit of 55 excess lifetime cancer cases. Other models have been proposed by various investigators for extrapolating from high exposure levels to low levels. The use of these other models to estimate excess cancers results in a range of 52 to 417 excess cancer cases.

DHS staff also examined the compatibility of the animal-based potency factor with the epidemiologic data from two cohorts of workers occupationally exposed to ethylene oxide. The potency factor obtained by fitting the multistage model to the rat leukemia data was used to predict leukemia deaths among workers exposed to ethylene oxide. The resulting predictions were compatible with the number of leukemia deaths observed in the epidemiologic studies.

II. EVALUATION OF ETHYLENE OXIDE

Ethylene oxide, a colorless gas at room temperature and pressure, is one of the 25 chemicals of highest production volume in the U.S. Natural sources are believed to be insignificant. Although no ethylene oxide is produced in California, it is distributed in the state for use in manufacturing surfactants (detergents), and for sterilization and fumigation. ARB staff estimates that about 360 tons of ethylene oxide were emitted into the state's atmosphere in 1985, with no significant change in annual emission rate since then.

The use of ethylene oxide as a sterilizing or fumigating agent is subject to regulation by the California Department of Food and Agriculture, because such use is as an economic poison. Therefore, although this report includes a discussion of overall ethylene oxide exposure, emphasis has been placed on exposure from sources which would be subject to regulation by the Air Resources Board. These sources include the manufacturing of surfactants and the distribution of ethylene oxide.

Exposure to Ethylene Oxide

General population exposure to ethylene oxide was estimated by modeling the emissions from all known sources in a portion of Los Angeles County. Using this approach, it is estimated that in 1985 nearly seven million people in the study area were exposed to a population-weighted annual average concentation of about 50 ppt (0.09 ug/m^3) of ethylene oxide. About 350,000 of these people were exposed to an average annual concentration of greater than 160 ppt (0.29 ug/m^3). Similarly, the exposures to people residing near large individual sources of ethylene oxide were estimated to range up to 17,000 ppt (31 ug/m^3), as determined by modeling emissions from these sources. Maximum short-term concentrations from such sources under worst-case meteorological conditions are estimated to be roughly four parts per million (4 ppm or 7200 ug/m^3). To determine exposures to people residing near sources of ethylene oxide not related to pesticidal uses, ARB modeled emissions from two ethylene oxide distributors. As the result of emissions from one of these, it is estimated that about 13,000 people are exposed to concentrations greater than 40 ppt (0.072 ug/m^3) ethylene oxide.

ARB staff believes that an approximation of the general population exposure in most less populous urban areas can be made by considering only the effect of hospital emissions on the calculated exposure of the Los Angeles area modeling study. This is because hospitals tend to be the major sources of emissions for smaller urban areas. By excluding the contribution due to non-hospital sources in the modeling study, the population-weighted annual average ethylene oxide concentration due only to hospital emissions was estimated to be 9 ppt (0.016 ug/m^3). This is reasonably consistent with the fact that in the modeling study, hospitals were responsible for roughly one-sixth of the overall emissions.

Ambient concentrations of ethylene oxide cannot be monitored using currently available techniques. Current detection limits are around 100,000 ppt (180 ug/m^3), which is several times higher than estimated annual average ambient concentrations. ARB staff obtained data from all known potential emitters of ethylene oxide within a significant portion of Los Angeles County. ARB staff then modeled these emissions to obtain population-weighted annual average ethylene oxide concentrations for people who were exposed to these emissions. These people were probably also exposed to ethylene oxide emissions from sources outside of the portion of Los Angeles County for which emissions were modeled, but that exposure could not be quantified in this study. A Gaussian air quality model (ISCST) was used to predict the ethylene oxide concentrations for a gridded array of receptors one kilometer apart, using meteorological data for a full year. Only annual average concentrations were estimated because no shorter-term acute health effects were anticipated.

In general, peak hourly concentrations estimated through application of the ISCST model agree with experimentally determined values within a factor of three. Agreement should improve as averaging times become longer. Therefore, annual average concentrations estimated through application of this model (as obtained for this report) should agree to a significantly greater extent. Modeled values in this report may differ from what might be monitored (had monitoring been possible) due to approximations made in estimating the emission rates from specific facilities, which were used as modeling inputs. Additionally, some emission sources could conceivably not be known to staff. Certain assumptions have been made in developing emissions data from particular sources. For example, if a range of time was reported during which emissions might occur, an average was used for modeling input. The total extent of errors resulting from assumptions such as these, although believed to be small, is difficult to quantify.

Limited data indicate that exposures to ethylene oxide from smoking and ingestion may exceed exposures from ambient air. Only one research citation exists for cigarette smoke concentrations, and only an upper bound estimate exists for possible daily intake rates from food and drink.

Sources of Ethylene Oxide in the Atmosphere

Ethylene oxide is emitted from four types of facilities in California, as follows in descending order of emissions: sterilization, fumigation, surfactant manufacture, and distribution. In addition, minor emission sources exist with varying emissions, and ethylene oxide is also emitted from combustion processes for which no quantification exists.

Roughly three-fifths of quantifiable ethylene oxide emissions in California result from sterilization, principally of medical devices and health care products. Although most of these emissions result from industrial sterilizers, most of the emitting sources are hospitals.

Virtually all of the ethylene oxide used in the process of sterilization (and also fumigation) is assumed to be emitted to the atmosphere. Fumigation of spices and related botanical products is believed to result in roughly one-third of quantifiable ethylene oxide emissions in California.

Less than a tenth of quantifiable emissions in California are ascribed to non-pesticidal sources, specifically, to surfactant manufacture and distribution of ethylene oxide. Most of the ethylene oxide emitted from surfactant manufacturing is assumed to be fugitive emissions from equipment leaks, although minimal data have been collected. Most of the emissions from distribution facilities result from the venting of residual gas from returned ethylene oxide-containing cylinders to the ambient air.

Environmental Fate of Ethylene Oxide

The most likely processes by which ethylene oxide could be removed from the atmosphere are reactions with hydroxyl radicals, hydrolysis, and wet deposition (washout by rain). Based on recent studies, both the reaction with hydroxyl radicals and hydrolysis would significantly reduce ambient concentrations of ethylene oxide only over a period of several weeks. Washout by rain is not expected to be a significant removal process due to the appreciable desorption rate of ethylene oxide from water solutions. Acidic fog occurs in certain heavily populated areas of California, and could reduce ambient ethylene oxide concentrations by up to five percent in those areas, assuming that ethylene oxide is destroyed whenever this meteorological phenomenon occurs. No significant pathways are believed to exist for the atmospheric generation of ethylene oxide.

During the sterilization/fumigation process for medical equipment and spices, ethylene oxide is not only exhausted directly to the ambient air, but can also be discharged with wastewater to local sewers. This is due to the use of water-sealed, once-through vacuum pumps for evacuating sterilizers, and the absorption of ethylene oxide by the water. Some companies in California recently installed closed-loop systems which can eliminate discharges to the wastewater. Ethylene oxide dissolved in wastewater is probably emitted into the ambient air before breakdown by hydrolysis can occur. Specifically, for common velocities of sewage flow, most of the ethylene oxide dissolved in wastewater is expected to evaporate within two miles of the point at which the ethylene oxide was introduced. This compares with an anticipated hydrolysis (or breakdown) rate for water (with acidity of the range encountered in sewage) on the order of days.

The fate of ethylene oxide is especially important in materials that come into close contact with people, such as surgical equipment, pharmaceuticals, and food service and packaging materials. Studies of the fate of residual ethylene oxide in these materials have established that it will degrade or evaporate. The information from these studies indicates that most of the residual ethylene oxide is no longer present in the materials after a period ranging from hours to several days.

Non-Cancer Health Effects

Acute, subchronic, and chronic exposures of humans and animals to ethylene oxide have been associated with a variety of noncarcinogenic adverse health effects. Acute exposure to ethylene oxide has resulted in a variety of adverse effects, including central nervous system (CNS) depression, mucous membrane irritation, respiratory tract irritation, loss of coordination, and convulsions. Dermatological effects such as burns and allergic reactions have been associated with ethylene oxide exposure. These adverse effects occur at exposures of at least 100 ppm (180,000 ug/m^3), which is twenty-five times higher than the maximum four ppm (7,200 ug/m^3) short term concentration predicted to result from large emission sources under worst-case meteorological conditions.

Symptoms of toxicity in animals following subchronic exposure to ethylene oxide are similar to those resulting from acute exposure, including neurotoxicity, respiratory tract irritation and hematological effects. Chronic and subchronic exposure of humans to ethylene oxide also produces symptoms of neurotoxicity. Following recurrent exposure to moderate to high levels of ethylene oxide, [up to 500 ppm (900,000 ug/m^3)] neurotoxic effects result, including incoordination, dizziness, and peripheral neuropathy.

Ethylene oxide has the potential to cause adverse reproductive effects in animals. These include fetal toxicity and embryotoxicity in rats, teratogenic effects (skeletal malformations) in mice, reduction of female reproductive potential in rats, reduction of fertility in male mice, and adverse effects on sperm of monkeys. One epidemiological study observed an association between ethylene oxide exposure and an increase in spontaneous abortions in hospital sterilizing staff.

Even for the maximum four ppm (7,200 ug/m^3) hourly concentration predicted to result from large emission sources under worst-case meteorological conditions, no acute or non-carcinogenic chronic effects are expected to occur.

Carcinogenic Effects

Ethylene oxide has been found to be carcinogenic in animals following subcutaneous, oral, and inhalation administration. Following oral admnistration, ethylene oxide produced an increase in local tumors (squamous cell carcinoma of the forestomach) in rats. Following inhalation, ethylene oxide produced a significant increase in mononuclear cell leukemia in male and female rats and an increase in peritoneal mesotheliomas in male rats. An increase in brain tumors (rarely found in control animals) was also observed in male rats exposed to ethylene oxide by inhalation.

Epidemiologic evidence has demonstrated an association between the exposure of humans to ethylene oxide and cancer. An excess of leukemia mortality has been reported in several epidemiological studies. However, these studies do not provide conclusive evidence due to the small numbers of workers studied and due to the possible exposure of the workers to other carcinogens. Still, the studies provide some evidence of ethylene oxide's carcinogenicity in humans.

In 1985, the International Agency for Research on Cancer (IARC) concluded that there is sufficient evidence for the carcinogenicity of ethylene oxide in animals, and that the evidence of carcinogenicity in humans is limited. Overall, based on both the animal and human data, IARC considered that ethylene oxide is probably carcinogenic in humans. DHS staff concurs with these conclusions. In addition, the DHS staff has found no evidence for a carcinogenic threshold level for ethylene oxide.

Risk Due to Atmospheric Ethylene Oxide

The DHS staff used dose-response data from a two-year inhalation study of rats (Snellings et al., 1984) to estimate the carcinogenic risk from ambient air exposure to ethylene oxide. Female rats exposed to 10, 33, and 100 ppm (corresponding to 18,000, 59,000, and 180,000 ug/m^3 respectively) of ethylene oxide for 6 hours/day, 5 days/week for two years developed mononuclear cell leukemia with incidences of 20%, 33%, and 38% respectively, compared to 12% in the unexposed controls. Cancer risk at ambient levels was estimated by extrapolating four orders of magnitude from the test levels of ethylene oxide using the linearized multistage model. This model produces a health-protective risk estimate because it is linear at low doses.

The range of risk values contains several sources of uncertainty: (1) statistical uncertainty due to the usual limited number of animals that is practical to use in bioassay, (2) the choice of the animal-to-human scaling factor; (3) the choice of the extrapolation models; (4) and the large range of extrapolation (four orders of magnitude) from the ethylene oxide concentrations used in the animal experiments to current ambient levels.

DHS staff examined the compatibility of the potency factor based on the animal data with the leukemia mortality of two cohorts occupationally exposed to ethylene oxide. Predictions based on the DHS risk model were very close to the number of observed leukemia deaths.

The DHS staff recommends that the range of risk for ambient exposures to ethylene oxide be based on the maximum likelihood estimate predicted by the multistage model and the upper 95% confidence limit. The range of estimated excess lifetime cancer risks from continuous (24-hour-per-day) lifetime exposure to average ambient airborne concentrations, estimated to be about 0.09 ug/m^3 (50 ppt) in the Los Angeles Basin, is 6 to 8 cases per million persons exposed. With an estimated population of 7 million in the Los Angeles Basin, exposure to ethylene oxide could result in 55 excess lifetime cancers. For comparison, the DHS staff used several other models proposed for cancer risk estimation by various investigators.

These models produced an upper limit range of 52 to 417 excess lifetime cancers.

Based on the findings of carcinogenicity and the results of the risk assessment, DHS staff finds that ambient ethylene oxide is an air pollutant which may cause or contribute to an increase in mortality or an increase in serious illness, or which may pose a present or potential hazard to human health.

III. SUMMARY OF ENVIRONMENTAL IMPACTS OF THE IDENTIFICATION OF ETHYLENE OXIDE AS A TOXIC AIR CONTAMINANT

The identification of ethylene oxide as a toxic air contaminant is not in itself expected to result in any environmental effects. The identification of ethylene oxide as a toxic air contaminant by the Board may result in the Board and air pollution control districts adopting toxic control measures in accordance with the provisions of state law (Health and Safety Code Section 39665 and 39666). Any such toxic control measures would result in reduced emissions of ethylene oxide to the atmosphere, resulting in reduced ambient concentrations, concurrently reducing the health risk due to ethylene oxide exposure. Therefore, the identification of ethylene oxide as a toxic air contaminant may ultimately result in environmental benefits. Environmental impacts identified with respect to specific control measures will be included in the consideration of such control measures pursuant to Health and Saety Code Section 39665 and 39666.

IV. REGULATORY BACKGROUND AND PROCEDURES

Division 26, Chapter 3.5 of the Health and Safety Code* (HSC) and Food and Agriculture Code Section 14021 et seq. set forth the procedure for identifying and controlling toxic air contaminants (TACs) in California. (These provisions were enacted in September 1983 as Assembly Bill 1807, Stats. 1983, ch. 1047.) The Department of Food and Agriculture is responsible for identifying and controlling TACs in their pesticidal uses. The ARB has authority over TACs in all other uses.

HSC Section 39650 sets forth the Legislature's findings about substances which may be TACs. The Legislature has declared:

> "That public health, safety, and welfare may be endangered by the emission into the ambient air of substances which are determined to be carcinogenic, teratogenic, mutagenic, or otherwise toxic or injurious to humans."

The findings also include directives on the consideration of scientific evidence and the basis for regulatory action. With respect to the control of TACs, the Legislature has declared:

> "That it is the public policy of this state that emissions of toxic air contaminants should be controlled to levels which prevent harm to the public health."

The Legislature has further declared that, "while absolute and undisputed scientific evidence may not be available to determine the exact nature and extent of risk from toxic air contaminants, it is necessary to take action to protect public health."

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* Health and Safety Code Section 39665; all statutory references are to the Health and Safety Code except as otherwise stated.

In the evaluation of a substance, the Legislature has declared that the best available scientific evidence, gathered from both public agencies and private sources including industry, should be used. The Legislature has also determined that this information should be reviewed by a scientific review panel and by the public.

The Board's determination of whether or not a substance is a toxic air contaminant includes several steps specified by the HSC. First, ARB staff requests the DHS to evaluate the health effects of a substance (Section 39660). The evaluation includes a comprehensive review of all available scientific data. Upon receipt of a report on health effects from DHS and in consideration of their recommendations, the ARB staff prepares and submits a report to the Scientific Review Panel (SRP) for its review (Section 39661). The report consists of the DHS report (Part B), material prepared by the ARB staff on the use, emissions and ambient concentrations of the substance (Part A), and public comments on the draft Report and Responses (Part C). It serves as the basis for future regulatory action by the Board. The report is also made available to the public, which may make comments on the report before it is submitted to the SRP.

After receiving the SRP's written findings that the report is not seriously deficient, the Board issues a public hearing notice and a proposed regulation identifying the substance as a toxic air contaminant. If, after a public hearing and other procedures to comply with Government Code Section 11340 et seq., the Board determines that a substance is a toxic air contaminant, its findings must be set forth in a regulation (Section 39662). The HSC also sets forth procedures for developing and adopting control measures for substances identified as TACs (Sections 39665-39667).

V. RECOMMENDATION

Based on the findings of carcinogenicity and the results of the risk assessment, the DHS staff finds that ethylene oxide meets the definition of a toxic air contaminant. The staff of the Air Resources Board, therefore, recommends that ethylene oxide be identified by the Board as a toxic air contaminant. In making this recommendation, the ARB and DHS staffs find that available scientific evidence is not sufficient at this time to support the identification of an exposure level below which carcinogenic effects would not have some probability of occurring, and recommend that ethylene oxide be treated as having no identified threshold.

REPORT TO THE AIR RESOURCES BOARD
ON ETHYLENE OXIDE

SUBMITTED TO THE SCIENTIFIC REVIEW PANEL FOR REVIEW

PART A - PUBLIC EXPOSURE TO, ENVIRONMENTAL FATE OF, AND SOURCES OF ATMOSPHERIC ETHYLENE OXIDE IN CALIFORNIA

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June 1987

Report to the Air Resources Board on Ethylene Oxide
Submitted to the Scientific Review Panel for Review

Part A - Public Exposure to, Environmental Fate of, and Sources of Atmospheric Ethylene Oxide in California

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INTRODUCTION

Ethylene oxide is a colorless, odorless gas with empirical formula C_2H_4O. This simple epoxide is an important industrial chemical used in sterilization and manufacturing processes in California. It is emitted into the atmosphere from (in descending order of emission quantities): sterilization use, fumigation use, use in manufacturing surfactant, and distribution processes. Based upon its gas-phase atmospheric reactivity, ethylene oxide has an estimated lifetime of 200 days or longer. Based on limited data, exposures resulting from smoking and ingestion may be greater than exposures to ethylene oxide from ambient air.

This report is an assessment of public exposure to atmospheric ethylene oxide in California, and includes information on the amount emitted, manner of usage, and persistence in the atmosphere. Community exposures and exposures of people living near large sources of ethylene oxide were determined from modeling the dispersion of emissions from these sources. Direct measurements of ambient levels could not be made because current monitoring methods are not sensitive enough to detect ethylene oxide at anticipated ambient concentrations. Emission data for dispersion modeling were obtained from the operators of industrial facilities and hospitals which use ethylene oxide.

This report also includes a review of chemical and physical properties of ethylene oxide used to determine emissions and atmospheric fate. Also included is a comprehensive discussion of the atmospheric chemistry and possible atmospheric removal processes of ambient ethylene oxide.

As a registered economic poison (pesticide), ethylene oxide is regulated by the California Department of Food and Agriculture in its use as a sterilizing or fumigating agent. Therefore, although this report includes a discussion of overall ethylene oxide exposure, emphasis has been placed on exposure attributable to sources (distribution processes and surfactant manufacturing) which would be subject to regulation by the Air Resources Board.

I. PUBLIC EXPOSURE TO ETHYLENE OXIDE

General population (or community) exposure to ethylene oxide was estimated by modeling the emissions of ethylene oxide from all known sources in a portion of Los Angeles County. A modeling approach was used because the highest levels of ethylene oxide anticipated to be found in the ambient air are about 20,000 parts per trillion (ppt)* and current detection limits for ambient monitoring analyses are greater than 100,000 ppt. Until a more sensitive method for detecting ambient ethylene oxide is developed, dispersion modeling of emission sources will remain the best approach for estimating ambient ethylene oxide concentrations. Using this modeling approach, it is estimated that in 1985 nearly seven million people in the study area were exposed to a population-weighted annual average concentration of about 50 ppt of ethylene oxide. This is the exposure level to which the average person in the area is exposed, in excess of any background level.

Similarly, the exposures to people residing near large individual sources have been estimated by modeling the emissions from some of these sources. Annual exposures for people living near large individual sources of ethylene oxide were estimated to range from 2,400 to 17,000 ppt. Maximum one-hour concentrations under worst case meteorological conditions from such sources are estimated to be approximately four parts per million. Of the sources of ethylene oxide not related to pesticidal uses, emissions from one distributor of ethylene oxide cylinders, when modeled, resulted in the estimated exposure in 1985 of approximately 13,000 people to concentrations greater than 40 ppt

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* 1,000 parts per trillion equals one part per billion, which for ethylene oxide equals 1.8 micrograms per cubic meter.

ethylene oxide. Limited data indicate that exposures to ethylene oxide from smoking and ingestion may exceed general population exposures from ambient air.

In general, peak hourly concentrations estimated through application of the ISCST model (used in this report) agree, within a factor of three, with short-term concentrations experimentally determined. ARB staff believe that as the averaging times lengthen, the correlation improves. Thus, the annual average concentrations estimated through application of this model (as estimated for this report) are expected to be well within a factor of three of the actual concentration resulting from identified emissions. Modeled values in this report may otherwise differ from what might have been monitored (had monitoring been possible) due to approximations made in estimating the emission rates or times from specific facilities, which were used as modeling inputs. For example, if a facility reported a range of time over which ethylene oxide might be released, the average was used. Additionally, some emission sources could conceivably not be known to staff. Estimates of errors in emission estimates, although believed to be small, are difficult to quantify.

The following section, Section A, presents a discussion of exposure to estimated ambient levels of ethylene oxide. Estimates were based on emissions from all known sources of ethylene oxide in a portion of Los Angeles County. Section B includes estimates of exposure near emission sources of ethylene oxide. This section gives estimated exposures only for sources that would be under the Air Resources Board's (ARB's) jurisdiction. Section C includes a discussion of routes of exposure to ethylene oxide other than from the ambient atmosphere.

A. AMBIENT AIR EXPOSURE

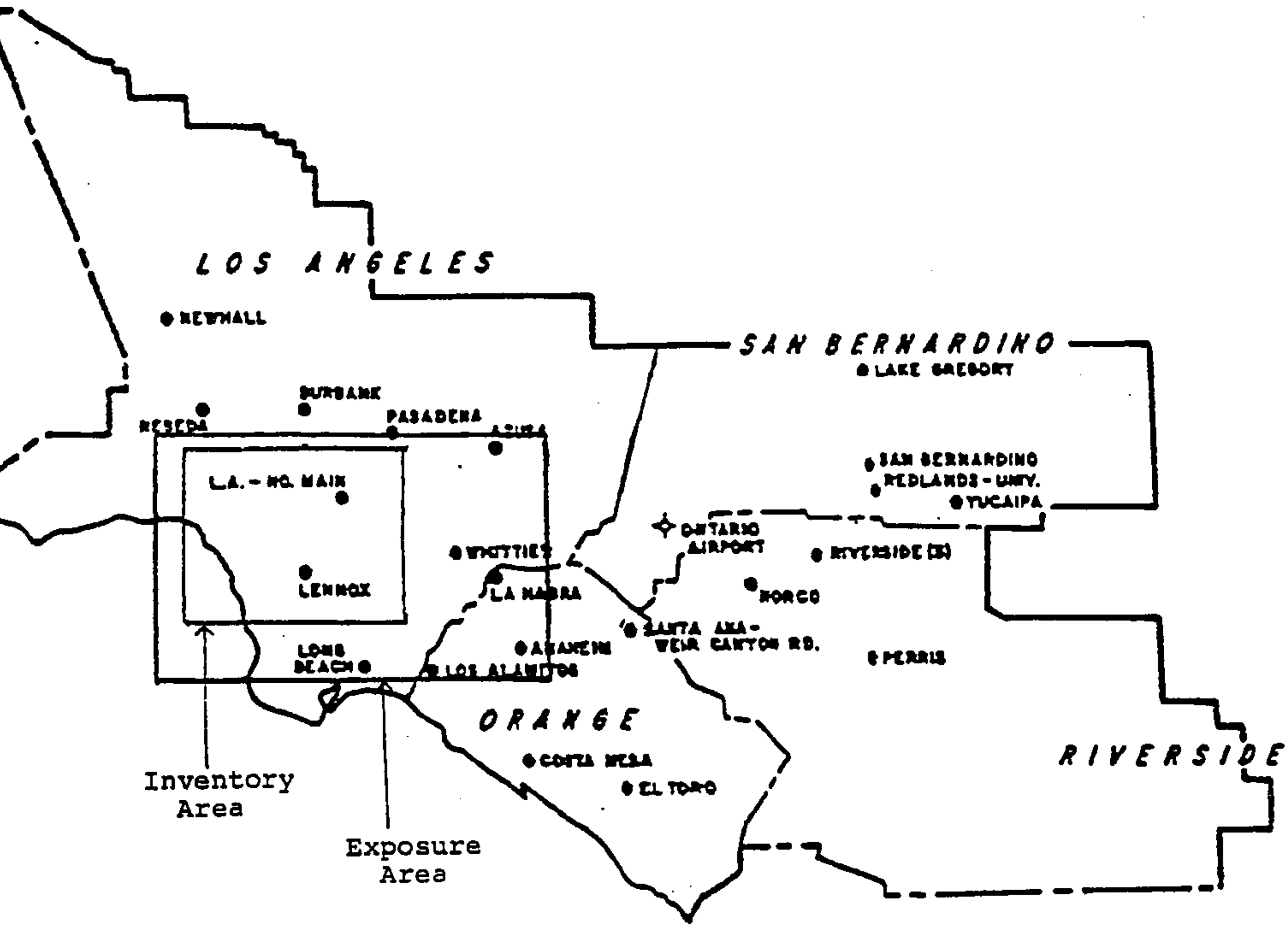
Because monitoring data cannot be obtained for ambient concentrations, the ARB staff modeled the emissions from all known sources of ethylene oxide within an area of Los Angeles County. The results of this analysis provide an approximation of the results which might be achieved if an ambient monitoring network had been set up in that area. The modeling study estimates exposures resulting from both non-pesticidal uses that could be regulated by the ARB, and pesticidal uses that could be regulated by the Department of Food and Agriculture. The results of this analysis allow an assessment of the risk from ethylene oxide exposure in the ambient air for a portion of the South Coast Air Basin. Based on the results of this study, an estimate was also made of statewide exposure.

To estimate ambient exposure to ethylene oxide, the ARB staff modeled ethylene oxide emissions from all known sources within a major portion of Los Angeles County for 1985. This area, called the inventory area, included ethylene oxide emissions from 55 hospitals, one large commercial sterilization facility, and two compressed gas repackaging facilities. The detailed inventory for this area included emission rates and times of release. Because significant concentrations from the inventory area disperse beyond the inventory area boundaries, exposures were estimated for a larger rectangular area called the exposure area (see Figure I-1). The ambient concentrations of ethylene oxide in the exposure area could be greater than that predicted by this modeling effort due to emissions dispersing into the exposure area from sources located outside of the inventory area.

The modeling study indicates that the approximately seven million people in the exposure area were exposed to a population-weighted annual mean

Figure I-1

MAP OF ETHYLENE OXIDE MODELING AREA



ethylene oxide concentration of about 50 ppt in 1985. Approximately 50 percent of the modeled area's residents (3.5 million) were exposed to at least this annual concentration. The most exposed 5% of the population (about 350,000 of these people) were exposed to an average annual concentration of greater than 160 ppt. Figure I-2A shows the modeled ambient concentrations of ethylene oxide in the exposure area, and Figure I-2B shows the population distribution in the study area included in the modeling analysis.

Data supplied by the hospitals and by the three other facilities were used to determine emissions from each facility in the inventory area. The Gaussian air quality model Industrial Source Complex Short Term (ISCST) was used to predict population-weighted annual average ethylene oxide concentrations for a gridded array of receptors spaced one kilometer apart. All of the non-hospital sources, and 49 of the 55 hospitals, were modeled using meteorological data measured at the Los Angeles International Airport during 1978. This year was selected because it is the most recent year for which hourly readings are available and it also represents a poor year in terms of pollutant dispersion throughout the South Coast Air Basin. The remaining six hospitals, all located near the southern edge of this inventory area, were modeled using meteorological data measured at Long Beach Airport in 1962. For the exposure estimates, the population contained in each one kilometer square grid cell was assumed to be exposed to the ethylene oxide concentration estimated for the receptor node located at the center of the cell. A detailed description of the data collected, the methods used and the results of the modeling analysis are given in Appendix C.

FIGURE I-2A

ETHYLENE OXIDE CONCENTRATIONS IN THE EXPOSURE AREA FROM ALL SOURCES IN THE INVENTORY AREA

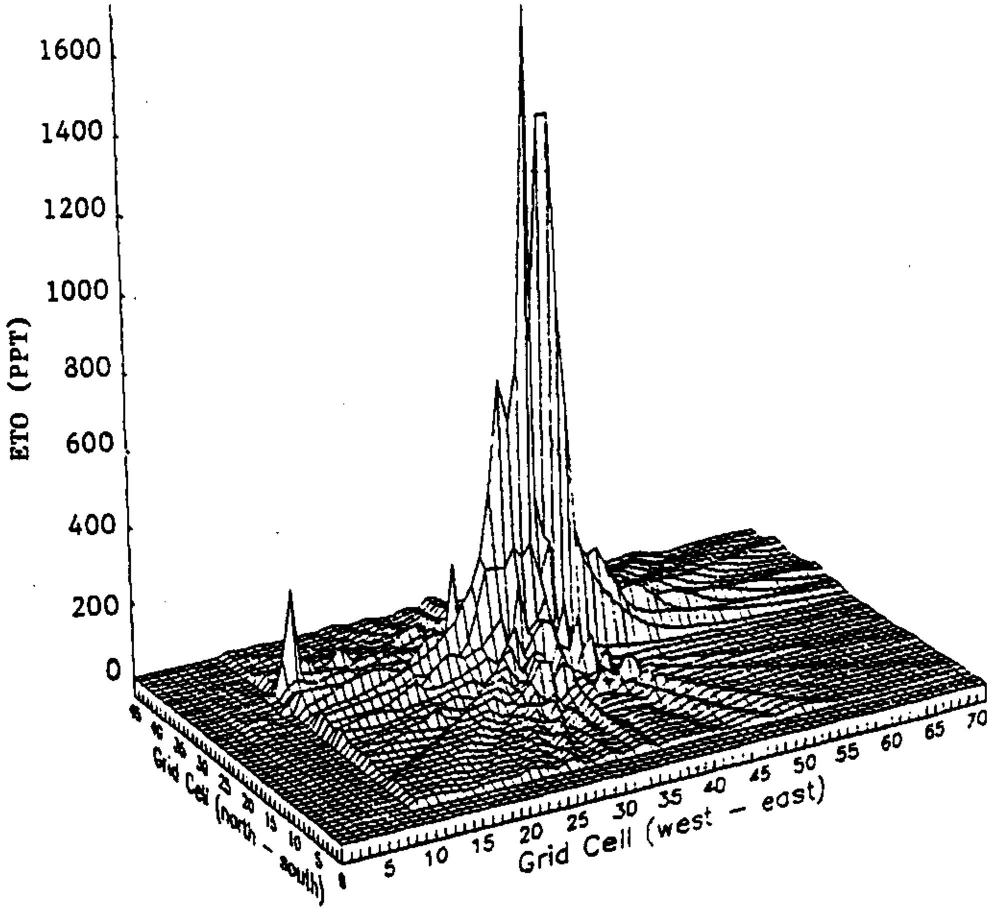
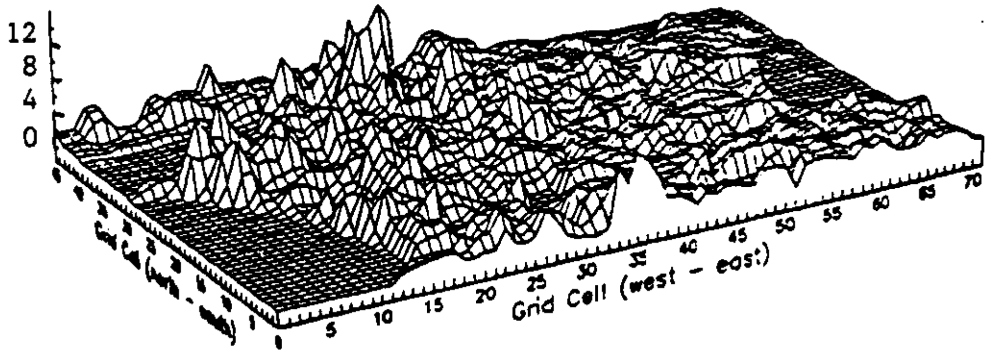


FIGURE I-2B

1985 POPULATION DISTRIBUTION IN THE EXPOSURE AREA (thousands people/cell)



ARB staff believes that a rough approximation of the general population exposure in other urban communities can be made by considering only the effect of hospital emissions on the calculated exposure of the modeling study. This is because hospitals tend to be the major sources of ethylene oxide emissions for most urban areas. By excluding the contribution due to the three non-hospital sources in the exposure area, the population-weighted annual average ethylene oxide concentration for the exposure area due only to emissions from hospitals was estimated to be 9 ppt. This estimate could be either an overestimate or an underestimate of the actual population-weighted exposure because several factors which were not amenable to quantification were not accounted for in making this estimate. Factors which would tend to make this an overestimate are the over-representation of large hospitals in the inventory area, the use of meteorological data for a year with poor dispersion, and the high population density in the exposure area. Factors which would tend to make this an underestimate are the exclusion of industrial sources, and the exclusion of emissions which disperse into the exposure area from hospitals located outside the inventory area. Appendix G contains a more detailed discussion of the uncertainties involved in making this estimate. Figure I-3A shows the modeled ethylene oxide concentrations due to hospital emissions, while Figure I-3B again shows the population distribution in the South Coast exposure area.

B. EXPOSURE CLOSE TO SOURCES

To evaluate exposure to ethylene oxide experienced by people living in close proximity to emission sources, the exposure resulting from emissions from a number of industrial users of ethylene oxide was determined. Of

Figure I-3A

ANNUAL ETHYLENE OXIDE CONCENTRATIONS FROM ALL HOSPITALS IN THE INVENTORY AREA

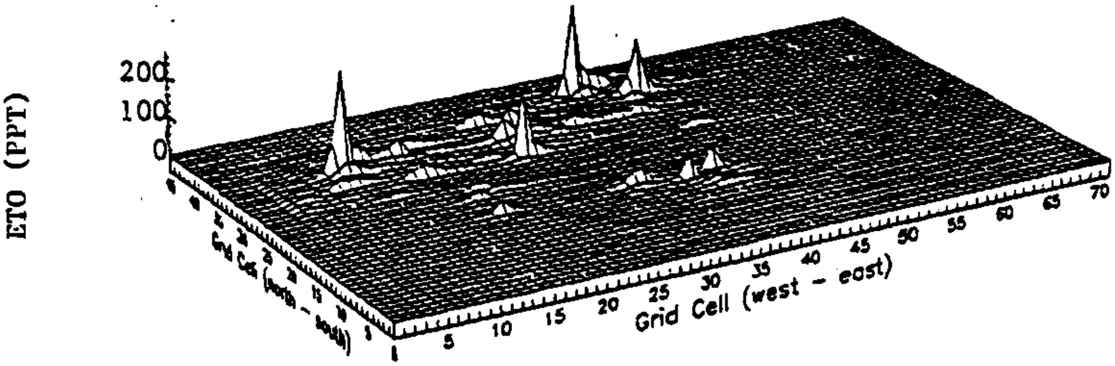
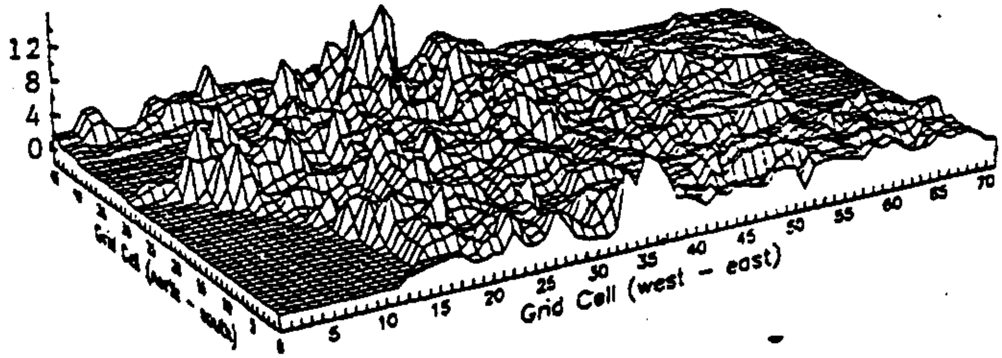


Figure I-3B

1985 POPULATION DISTRIBUTION IN THE EXPOSURE AREA (thousands people/cell)



particular concern to ARB is the exposure resulting from non-pesticidal uses of ethylene oxide, which are subject to ARB's jurisdiction for control measure development under AB 1807. Ethylene oxide distribution facilities are the principal non-pesticidal emission sources in California.

To estimate the exposure from ethylene oxide distributors, ARB used a dispersion model to estimate exposure from two facilities in the Los Angeles area. Both facilities were included in the ambient exposure analysis presented in Section A. The major source of emissions from each of the two facilities is the disposal of residual gas in ethylene oxide-containing compressed gas cylinders returned for refilling. Modeling studies were conducted for two of the five ethylene oxide distribution facilities located in California.

Table I-1 presents the estimated 1985 incremental and cumulative ethylene oxide exposure distributions for each of these two facilities in the South Coast Air Basin, as obtained by conducting ISCST modeling of emissions from the two compressed gas distribution facilities. The emissions from each source are estimated to have resulted in ethylene oxide exposures to about five million residents. Figures I-4 and I-5 present exposure curves derived from the cumulative population exposure estimate in Table I-1. Liquid Carbonic Corp. emissions are estimated to have led to 8,000 people being exposed to an annual average concentration of 40 ppt or higher; and from MG Industries emissions, 13,000 people are estimated to have been exposed to 40 ppt or higher.

Appendix D presents pictorial representations of the spatial distributions of concentrations due to emissions from the two distributors, as well as the resultant population exposure. The appendix also includes a discussion of

Table I-1

EXPOSURE DISTRIBUTION DUE TO TWO ETHYLENE OXIDE DISTRIBUTION FACILITIES FOR 1985

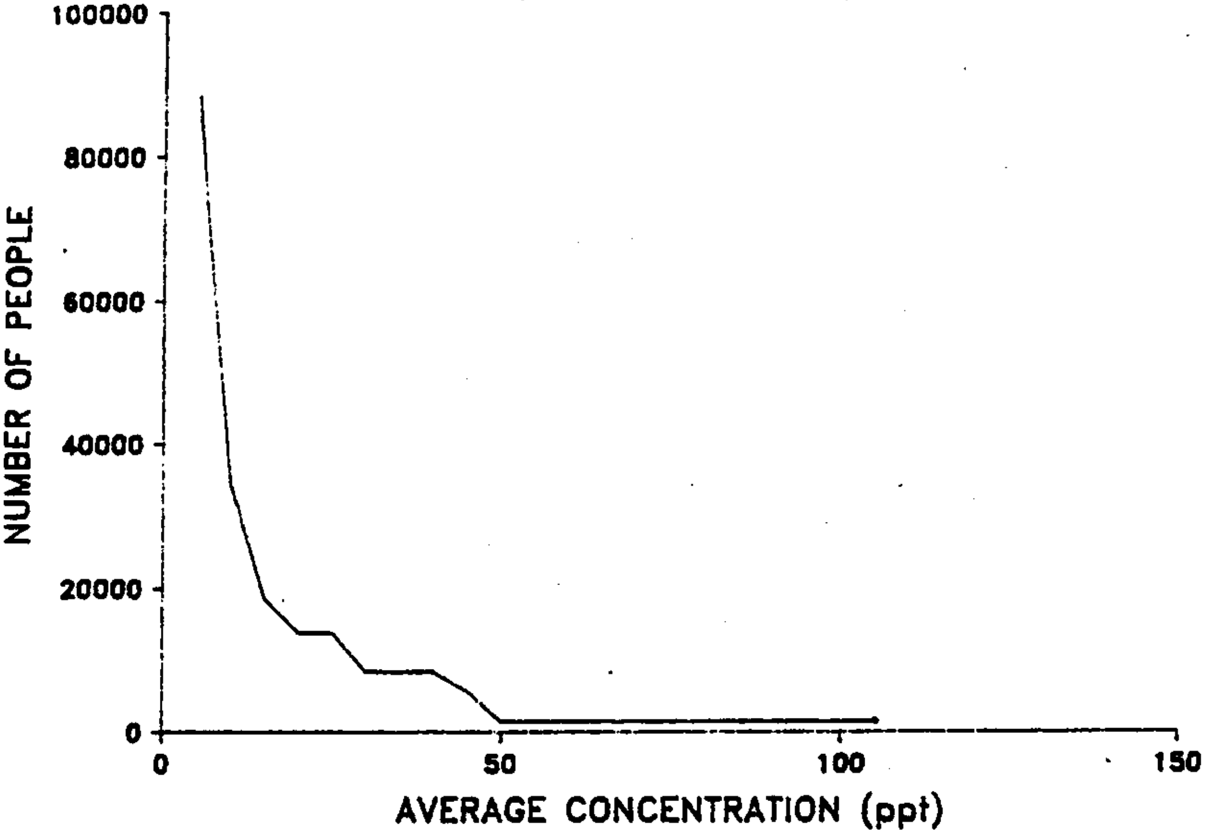
Annual Exposure Range (ppt)	Population Exposed			
	Liquid Carbonic Corp		MG Industries	
	Incremental	Cumulative	Incremental	Cumulative
5 - 10	53,696	88,353	140,749	253,258
10 - 20	20,806	34,657	65,604	112,609
20 - 30	5,387	13,751	21,518	47,005
30 - 40	0	8,364	12,002	25,487
40 - 50	6,925	8,364	4,291	13,485
50 - 60	0	1,439	5,036	9,194
60 - 70	0	1,439	0	4,158
70 - 80	0	1,439	0	4,158
80 - 90	0	1,439	0	4,158
90 - 100	0	1,439	4,158	4,158
100 - 110	1,439	1,439		

Total Exposed Population: 5,032,517
(4,944,164 people exposed to
concentrations greater than
0 ppt but less than 5 ppt)

4,904,695
(4,651,437 people exposed to
concentrations greater than
0 ppt but less than 5 ppt)

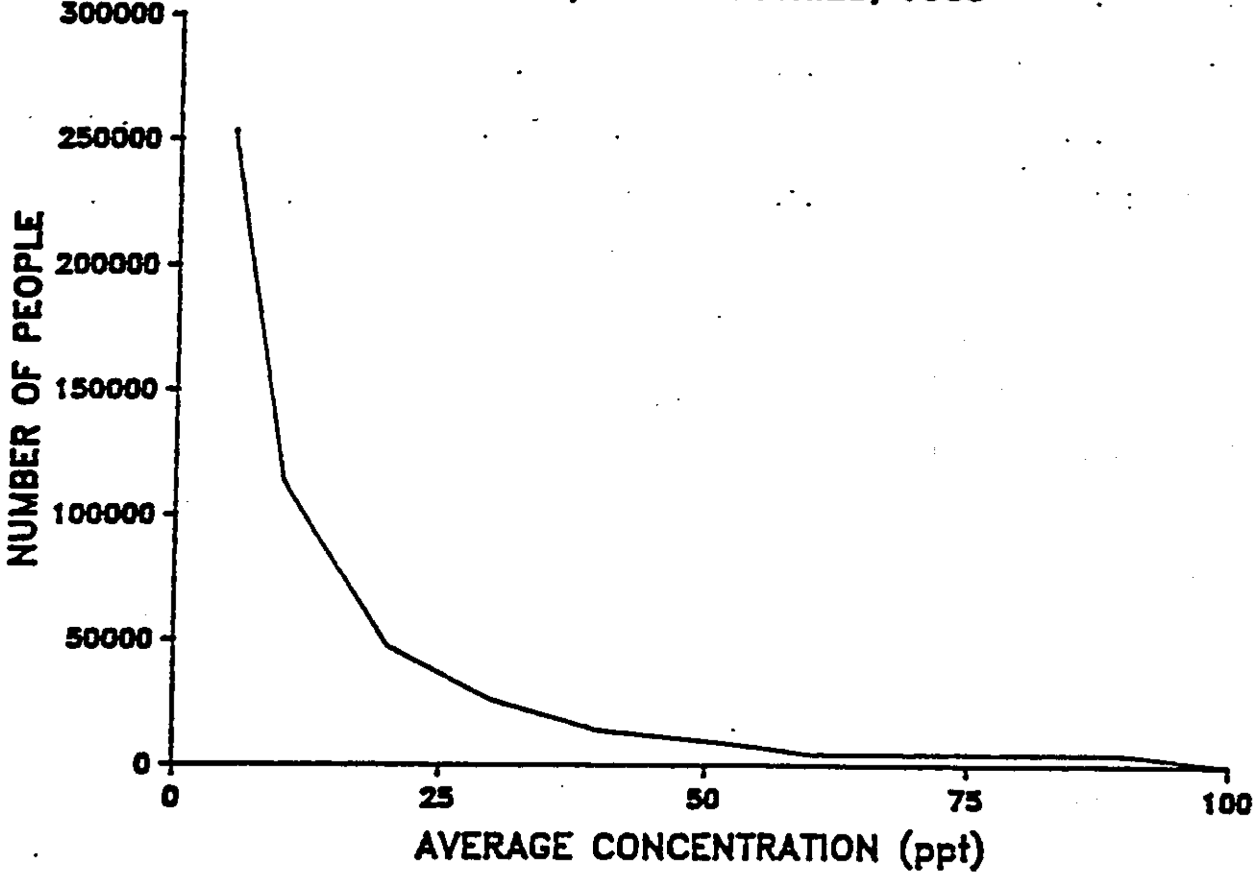
CUMULATIVE POPULATION EXPOSED TO ETO

FIGURE I-4, LIQUID CARBONIC, 1985



CUMULATIVE POPULATION EXPOSED TO EtO

FIGURE I-5, MG INDUSTRIES, 1985



modeling data, methods and results.

Table I-2 presents estimates of the population-weighted 1985 average and upper five percentile ethylene oxide concentrations from the two distribution facilities.

Table I-2

POPULATION WEIGHTED ANNUAL AVERAGE AND
UPPER FIVE PERCENTILE ETHYLENE OXIDE CONCENTRATIONS
FOR STUDY AREA

Source	Mean (ppt)	Upper 5% (ppt)	Study Area Population
Liquid Carbonic Corp.	0.8	4.8	5,000,000
MG Industries	1.6	10.0	4,900,000

Note: Population numbers have been rounded off to two significant figures.

The maximum annual concentration at any receptor downwind from Liquid Carbonics, Inc. is about 103 ppt, while the maximum annual concentration due to MG Industries is about 94 ppt. These concentrations are in addition to any background concentrations, or contributions from other sources.

A detailed discussion of exposure to ethylene oxide due to emissions from pesticidal sources is presented in Appendix D.

C. EXPOSURE THROUGH OTHER MEDIA

Although the primary focus of this report is ambient air exposure to ethylene oxide, exposure could also occur from ingestion of ethylene oxide found in drinking water and food products, and from smoking. The information available for ethylene oxide in these other media is very limited, and the data bases differ greatly. Table I-3 attempts to compare possible exposures from these sources.

Table I-3

POSSIBLE EXPOSURE TO ETHYLENE OXIDE THROUGH OTHER MEDIA

Route	Exposure (micrograms per day)
Ambient air inhalation	.02 ug/day (@ 50 ppt conc.)
Food ingestion	10 ug/day (upper limit)
Tobacco smoke inhalation	140 ug/day (for smoker)

Notes:

1) No estimate is available for exposures which may occur from drinking water or from breathing ethylene oxide off-gassing from fumigated products. See text for further discussion.

2) Assuming the validity of one study (Binder and Linder, 1972), ARB staff calculated that people who smoke one pack of cigarettes per day are exposed to approximately 140 micrograms (ug) per day from the smoke.

3) No other man-made sources of ethylene oxide emissions were identified and no significant natural sources of ethylene oxide are known.

4) See Appendix E for calculations of inhalation and ingestion rates.

According to the National Toxicology Program (NTP, 1985), "Based on its presence in food, food additives, or food packaging, potential daily intake of ethylene oxide per person in the United States has been estimated to be ten micrograms (FDA communication)." The ten microgram estimate is not based on any experimental measurements, but was calculated by assuming an upper bound to possible ethylene oxide concentrations in food. See Appendix E for details and calculations.

Off-gassing from spices fumigated with ethylene oxide represents the only identified source of indoor air exposure. This exposure is not likely to be significant for the following reasons. First, consumers use and stock at home relatively small quantities of spices. Second, EPA restricts ethylene oxide residues in ground spices to 50 ppm or less upon leaving the packing facility

(21 CFR 193.200(c)). Third, as discussed in Section II, ethylene oxide volatilizes relatively rapidly from spices. Presumably, when consumers purchase spices, most of the residual ethylene oxide would be gone.

Although no data were available regarding ethylene oxide concentrations in drinking water, the following factors are believed to limit human exposure from this route (EPA, 1985a). First, evaporation from water appears to be a significant removal process, as discussed in Section II. Second, chlorination used in water treatment plants presumably reduces the likelihood of human exposure, by oxidizing ethylene oxide.

II. PROPERTIES AFFECTING ENVIRONMENTAL FATE

Although epoxides as a group are considered to be relatively reactive, ethylene oxide has been shown to be fairly stable under most naturally occurring conditions and is relatively persistent in the atmosphere.

In addition to being emitted directly to the atmosphere, ethylene oxide readily volatilizes from water and sterilized products. Once in the atmosphere, ethylene oxide has been determined to persist long enough so that community exposure is not significantly reduced by its atmospheric breakdown.

A. PHYSICAL AND CHEMICAL PROPERTIES

Ethylene oxide is a colorless, flammable gas at room temperature and pressure condensing to a liquid at about 51°F. It is highly soluble in water and many organic solvents. Liquid ethylene oxide is miscible (capable of being mixed in all proportions) with water, alcohol, acetone, benzene, ether, and most organic solvents. Table II-1 contains data on physical properties of ethylene oxide.

Chemically, ethylene oxide is the simplest and most important member of the class of cyclic ethers known as epoxides, and is also known chemically as epoxyethane or oxirane. Epoxides are compounds with a molecular structure consisting of a three-membered ring in which the members are two carbon atoms and one oxygen atom. See Figure II-1 shows the chemical structure of ethylene oxide.

TABLE II-1

PHYSICAL PROPERTIES

Liquid

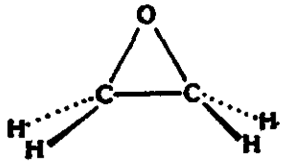
Apparent Specific Gravity, 20/20°C (68/68°F)	0.8711
Weight per gal. at 20°C (68°F)	7.249 lb.
Coefficient of Expansion at 20°C (68°F)	0.00161
Water Solubility	Complete
Heat of Vaporization at 1 atm	249.5 Btu/lb
Flash Point, open or closed cup	0°F
Freezing Point	-170.5°F -112.5°C
Boiling Point	50.9°F 10.5°C

Vapor

Critical Temperature	195.8°C (319.6°F)
Critical Pressure	1.043 psia
Auto-ignition Temperature in Air at 1 atm	428°C (802.4°F)
Decomposition Temperature of pure vapor at 1 atm	571°C (1059.8°F)
Heat of Combustion of gas, gross	308.7 kcal/g-mole
Heat of Decomposition of gas	20.0 kcal/g-mole
Henry's Law constant (dimensionless form, ratio of aqueous phase concentration to vapor phase concentration)	6.2

Figure II-1

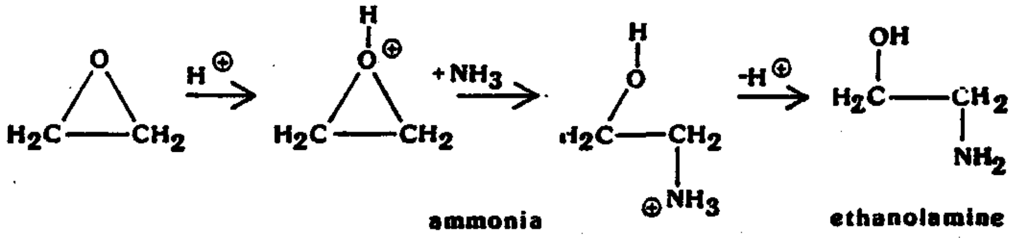
STRUCTURE OF ETHYLENE OXIDE MOLECULE



Many important industrial chemicals can be manufactured by adding various reagents to ethylene oxide. These include ethylene glycol and other glycols and glycol ethers, and ethanolamines. Figure II-2 shows the chemical reactions by which ethanolamine is produced by addition of ammonia to ethylene oxide.

Figure II-2

SYNTHESIS OF ETHANOLAMINE FROM ETHYLENE OXIDE

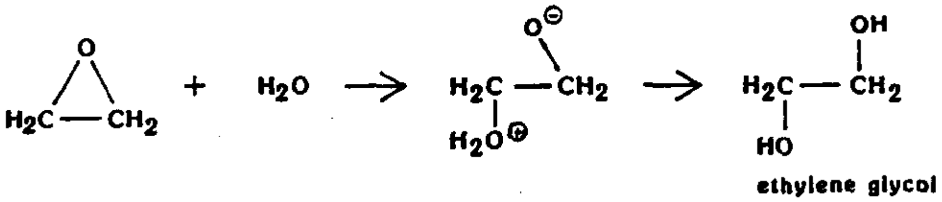


Most reactions of ethylene oxide involve opening the epoxide ring with strong acid or strong base. Figure II-3 shows hydrolysis mechanisms by which water adds to ethylene oxide to yield ethylene glycol. Although all three mechanisms occur whenever ethylene oxide is in water, one reaction usually predominates depending upon pH. The mechanisms are as follows: A) neutral pH, B) acidic pH, and C) basic pH. Rate equations and rate constants (k) at 25°C (77°F) are also provided (Bogyo, 1980) for each mechanism.

Figure II-3

Hydrolysis mechanisms of ethylene oxide to ethylene glycol

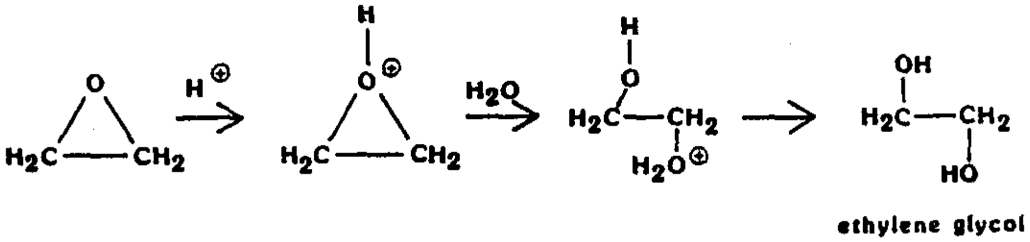
A) Neutral pH (predominates at pH between 5 and 11)



$k_N = 5.7 \times 10^{-7}$ second^{-1}

Rate = k_N x EtO concentration

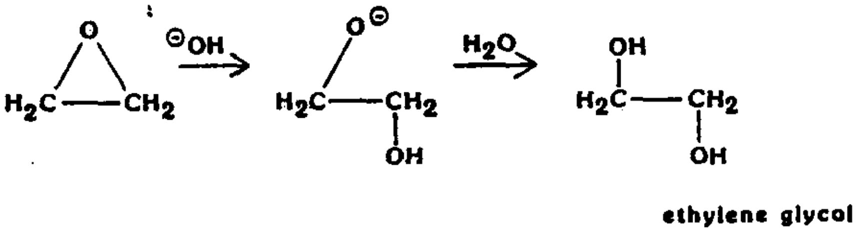
B) Acidic pH (Predominates at pH 3 or lower)



$k_A = 90 \times 10^{-4}$ liter mole^{-1}second^{-1}

Rate = k_A x EtO concentration x hydrogen ion concentration

C) Basic pH (Predominates at pH 12 or higher)



$k_B = 1 \times 10^{-4}$ liter mole^{-1}second^{-1}

Rate = k_B x EtO concentration x hydroxide ion concentration

B. PROPERTIES IMPORTANT FOR ESTIMATING EMISSIONS

During the sterilization/fumigation process for medical equipment and spices, ethylene oxide is not only exhausted directly to the ambient air, but can also be discharged with wastewater to the local sewers. This is due to the use of water-sealed vacuum pumps for evacuating sterilizers, and the solvation of ethylene oxide by the water. This is discussed further in Appendix D. Some California companies have recently installed closed-loop vacuum pump systems which can eliminate discharges to wastewater (Chemrox, 1987). In addition, sterilized products may contain some ethylene oxide residues. The following subsections present information that is important in estimating emissions into the atmosphere from wastewater and sterilized products. This information indicates that ethylene oxide dissolved in wastewater is probably emitted into the ambient air before breakdown by hydrolysis can occur. Tests performed on sterilized spices and manufactured goods are also discussed, which indicate that most ethylene oxide residues are removed by volatilization within a few weeks.

1) Properties in Water

a) Volatilization from Water

In general, the volatilization or desorption rate for a volatile chemical across a gas-liquid interface will follow first-order kinetics. For a first-order process, the rate of volatilization at any time is proportional to the concentration of the chemical in solution and can be described by the equation,

$$-\frac{dC}{dt} = K_d C \qquad (1)$$

C is the concentration of the chemical, $-dC/dt$ is the instantaneous change in concentration per unit of time (or rate of desorption), and K_d is the desorption coefficient for the chemical. If a chemical has a high desorption coefficient, then the chemical will volatilize rapidly from solution.

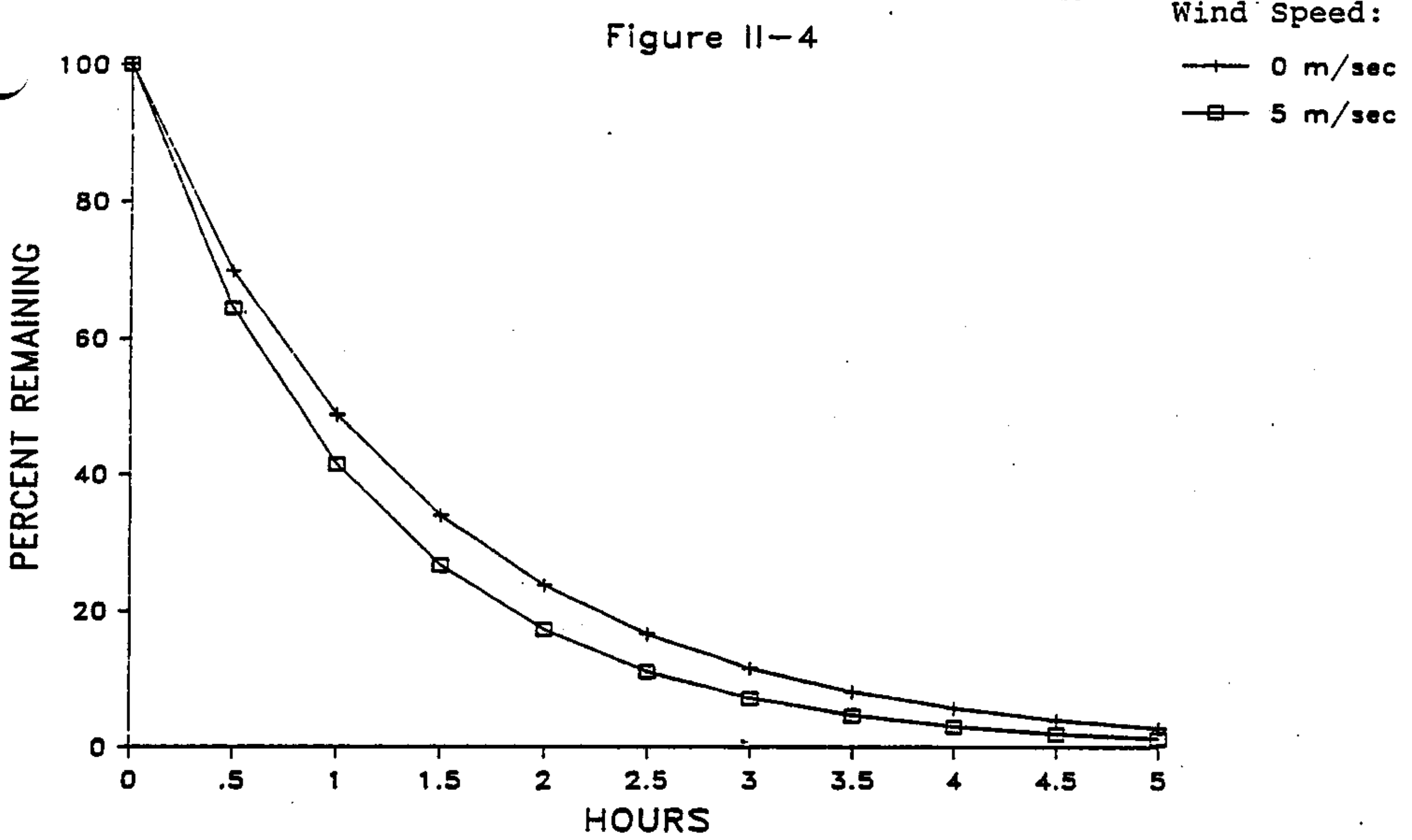
Desorption coefficients for ethylene oxide in water have been determined experimentally at 22°C. (71.6°F.) (Conway, 1983). Tests were conducted both with a five meter-per-second (11 miles per hour) wind flow over the liquid surface, and with no induced wind flow. After the addition of ethylene oxide into water, the dissolved ethylene oxide concentration was determined at various times by using direct aqueous injection into a gas chromatograph. Desorption coefficients of 0.72 per hour (no wind) and 0.88 per hour (5 meter sec^{-1} wind) were obtained.

The desorption coefficient for ethylene oxide (no wind) has also been calculated from a theoretical equation using measured oxygen desorption rates (Liss and Slater, 1974; Conway, 1983). This calculated desorption coefficient for ethylene oxide (0.68 per hour) compares favorably to the ethylene oxide desorption coefficient which was determined experimentally (0.72 per hour-no wind).

Figure II-4 shows the percentage of ethylene oxide remaining in the water over time, as derived from Conway (1983). Although the desorption rate is higher with wind present, the desorption half-life in both cases is less than one hour. Figure II-5 shows the fraction of ethylene oxide remaining versus distance from the discharge source for three discharge velocities. Sewer grades are selected to provide a minimum velocity of 2 feet per second (fps) and a maximum velocity of 8 fps (Zilly, 1975). Flatter grades (with slower velocities) are preferred so as to minimize excavation and pumping costs. At 2.9 fps, considered a common velocity, half of the discharged ethylene oxide will be removed within two miles of the discharge point. In addition, any

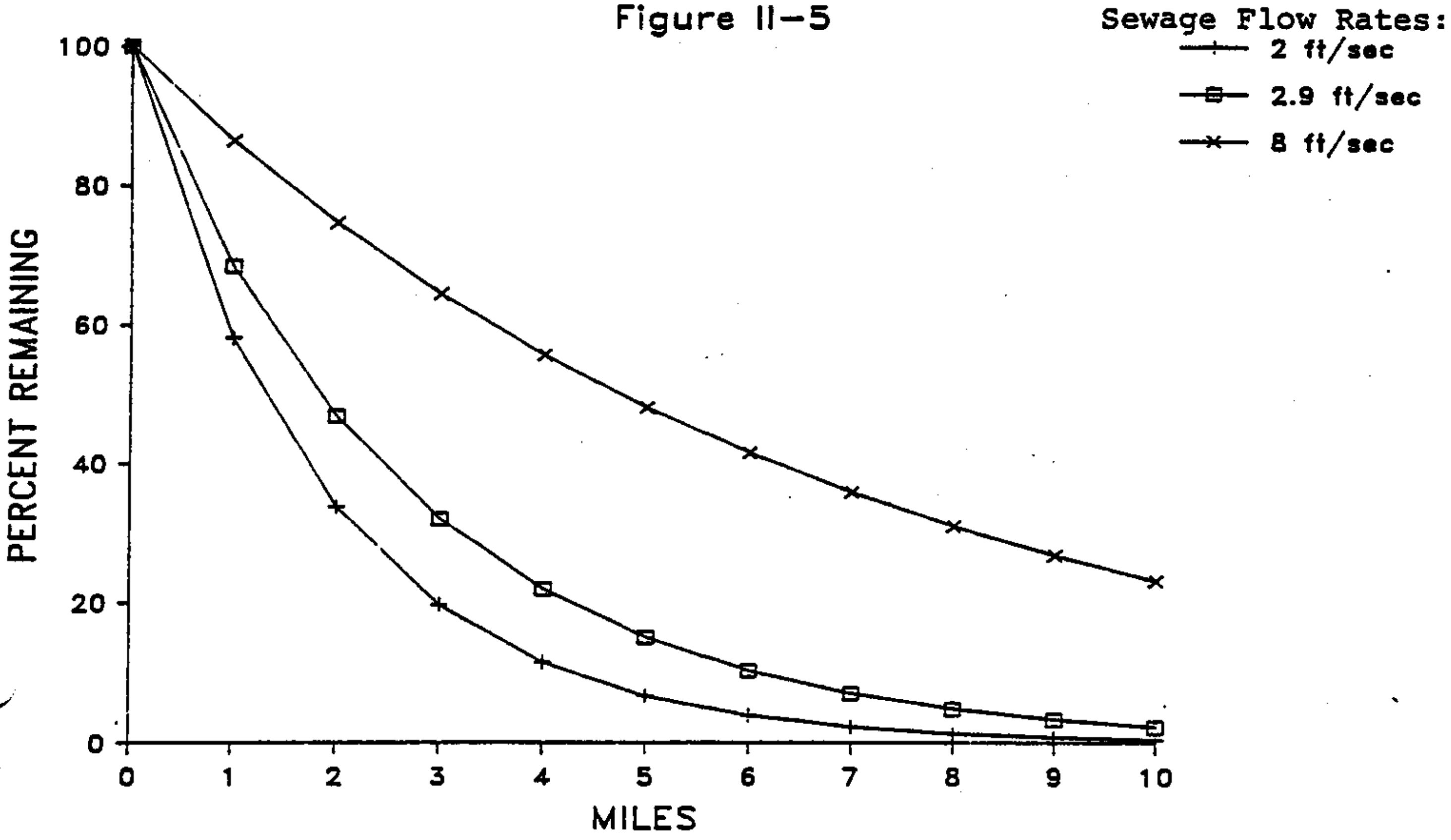
ETHYLENE OXIDE EVAPORATION FROM WATER

Figure II-4



ETHYLENE OXIDE EVAPORATION FROM WATER

Figure II-5



ethylene oxide which reached a wastewater treatment plant would pass through an aeration lagoon. Such aeration should be effective at desorbing any remaining ethylene oxide. Because wastewater pH is usually between 5 and 9, ethylene oxide is not expected to hydrolyze in wastewater at a significant rate (see subsection b below).

Therefore, ARB staff believes that most of the ethylene oxide which is discharged into wastewater (ranging up to 40% of a sterilizer load) will volatilize into the ambient air close to the discharge point. See Appendix G for a discussion of how these concepts were applied for modeling emissions.

b) Degradation in Water

Chemical degradation in water occurs only by hydrolysis involving cleavage of the carbon-oxygen bond of the cyclic ether to yield ethylene glycol, as was shown in Figure II-3. Bond cleavage occurs rapidly only under strongly acidic or strongly basic conditions. Ethylene oxide is stable and its rate of degradation does not vary significantly within the range of pH 5 to pH 9 found in natural waters and in sewer wastewater. The pH of sewer wastewater is generally between 5 and 9 because wastewater with pH outside this range can be corrosive to sewer lines. (Ordinances regarding wastewater pH have been passed where corrosion problems have been suspected. (SRWTP, 1986))

However, the rate of degradation is sensitive to changes in temperature (Conway, 1983). Hydrolysis is also a first order reaction. The rate constant may be estimated by (Bogyo, 1980):

$$\log K_n = 7.726 - 79.5/(.019\ T)$$

T = temperature (degrees Kelvin)

K_n = rate constant at neutral pH (pH = 7)

The half-life of ethylene oxide in water may be calculated as:

$$\text{half-life} = .693/K_n$$

Following are calculated half-lives of ethylene oxide dissolved in water at various temperatures, based on hydrolysis rates for neutral water (pH=7): 22 days at 20°C., 12 days at 25°C., 6.5 days at 30°C. (Bogyo, 1980).

Sewage temperatures generally do not vary as much as ambient air temperatures. As an example, sewage water temperature in Sacramento ranges from about 20°C. (68°F.) in winter to about 25°C. (77°F.) in summer (SRWTP, 1986) while ambient temperatures can vary from below 10°C. (50°F.) to over 32°C. (90°F.). As an inland city, Sacramento experiences a greater difference in ambient temperatures between seasons than is experienced by coastal cities. Therefore, coastal cities should have less sewage temperature variation than Sacramento.

Most ethylene oxide discharged to sewers enters the wastewater through the water-sealed vacuum pumps used to evacuate sterilizer chambers after sterilization is complete. The water temperature of the pump discharge is approximately the same as the temperature of the water supply, which varies with the season. A half-life of 12 to 14 days may be expected at normal water temperature, and has been experimentally measured in river water at 25°C. (77°F.) (Conway, 1983). Conway also estimated a half-life of greater than 20 days for bio-oxidation of ethylene oxide in the presence of micro-organisms.

In conclusion, ethylene oxide volatilizes from natural waters within a period of hours while hydrolysis occurs over a period of days. As a result, in a typical sewer system, most of the dissolved ethylene oxide would be expected to evaporate within two miles of its influent point (Figure II-5). Reactions with atmospheric water are discussed in subsection C.2.

2) Volatilization from Food Products and Manufactured Products

The fate of ethylene oxide is especially important in materials that come into close contact with people, such as surgical equipment, pharmaceuticals, and food service and packaging materials. The study of the fate of ethylene oxide in these materials has established that it will degrade to glycol (and halohydrin if halide is available), or evaporate (Wesley, 1965; Alguire, 1973; Gilmour, 1978). Scudamore and Heuser (1971) monitored some commercially treated products and found ethylene halohydrin residues but no ethylene oxide residues. The estimated vaporization rates suggested vaporization half-lives ranging from approximately four hours, up to 17.5 days for one of the studied commodities during cold storage. The effect of moisture content appeared varied and relatively small.

Alguire (1973) described losses of ethylene oxide from polystyrene creamer cups and cream cheese wrappers at ambient temperature and open to the environment. The ethylene oxide did not degrade on the polystyrene cups, and was lost solely through out-gassing. More than 90% evaporated by the first day, and no residual ethylene oxide was detected after five days. Ethylene oxide loss from cream cheese wrappers consisted primarily of conversion to ethylene glycol; no ethylene chlorohydrin was detected at any time. Ethylene oxide was undetectable by the tenth day.

After a review of available literature, EPA (1985) concluded: "In commodities, food containers, and manufactured goods, ethylene oxide appears to volatilize or hydrolyze to glycol or halohydrin with a half-life of about 2 weeks."

C. FATE IN THE ATMOSPHERE

It is often stated that because epoxides are fairly reactive, ethylene oxide would rapidly decompose in air. Although ethylene oxide does break down rapidly under aqueous ionic conditions, it is relatively unreactive to homogeneous gas-phase processes, which are the most common decomposition processes for organic substances in ambient air. The most likely removal processes for ethylene oxide are reactions with hydroxyl (OH) radicals, hydrolysis, wet deposition (washout by rain) and acid fog. Based on the most recent studies, both the reaction with hydroxyl radicals and hydrolysis would significantly reduce ambient concentrations of ethylene oxide only over a period of weeks. Washout by rain is not expected to be a significant removal process due to the appreciable desorption rate of ethylene oxide from water solution (Dana, 1984). Fog, if very acidic, could reduce ambient ethylene oxide concentrations, but only during such relatively uncommon meteorological conditions.

The exposure estimates in Section I rely on modeling the dispersion of emissions from ethylene oxide sources which occur over the course of hours. Because ethylene oxide concentrations that might arise from any release point are expected to decline much more rapidly from dispersion than from atmospheric breakdown, ethylene oxide was treated as a non-reactive compound for the modeling study. The discussion below presents the current state of knowledge about important removal mechanisms of ambient ethylene oxide.

1. Reactions with Free Radicals

The major atmospheric transformation process for most organic chemicals is reaction with hydroxyl radicals. Two measurements of the rate constant by the reaction of ethylene oxide with hydroxyl radical have been carried out. C. Zetzsch (1980) used flash photolysis/resonance fluorescence at 22°C. and obtained a rate constant of 5.3×10^{-14} cm^3 $molecule^{-1}$ sec^{-1}.
K. Lorenz and R. Zellner (1984) used laser photolysis/resonance fluorescence

at 25°C. and obtained a rate constant of 8.1×10^{-14} cm^3 $molecule^{-1}$ sec^{-1}. Both studies have error limits estimated at plus or minus 20%. These two measurements are reasonably consistent, resulting in a best estimate for the rate constant at room temperature of 7×10^{-14} cm^3 $molecule^{-1}$ sec^{-1} (Winer, 1986a). This rate constant corresponds to an atmospheric lifetime* of approximately 200 days or longer, showing that ethylene oxide will be long-lived if the only significant loss process is indeed gas phase reaction with hydroxyl radicals.

This finding is reasonably consistent with EPA's estimate (EPA, 1985a) that the lifetime of ethylene oxide is between 100 days and 215 days for a hydroxyl radical concentration of 1×10^6 molecules cm^{-3}, which has been reported as a reasonable estimate (Cupitt, 1983).

These recent studies, however, are in conflict with theoretical calculations of the atmospheric loss rate for ethylene oxide which had previously been published with no laboratory data. Dispersed in the atmosphere, reaction of ethylene oxide with hydroxyl radicals had been estimated to yield a half-life of 23 hours (Radding, 1977), 1.6 days (Brown, 1975), or 7.9 days (Cupitt, 1980). Calculations (performed through 1980) for the half-life of ethylene oxide in ambient air were based upon the belief that the hydroxyl radical would be as reactive toward ethylene oxide as it is toward other ethers, and that ethylene oxide would therefore degrade rapidly (Bogyo, 1980). With more recent documentation of the

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* "Lifetime" in this context means "natural lifetime". The half-life (defined as the time required for the concentration of reactant to fall to half of its original value) is equal to 69.3% of the natural lifetime.

reactivity of ethylene oxide with hydroxyl radicals, rapid degradation can no longer be anticipated. Based on the experimental data contained in the recent studies, the earlier calculations are now considered by ARB staff to overestimate the actual rate of removal of ethylene oxide.

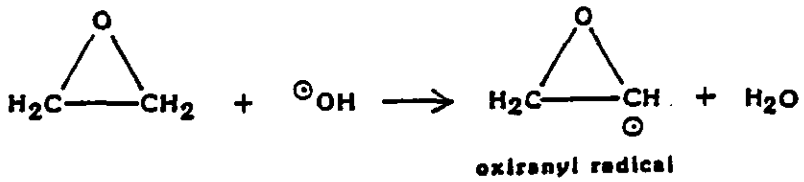
The atmospheric lifetime for ethylene oxide is longer than has been found for other ethers and epoxides. Ethylene oxide is more resistant to some types of free radical chemical attack than are other ethers and epoxides because of the unusual strength of its carbon-hydrogen bonds. As shown in Figure II-1, all hydrogen atoms are attached to carbon atoms of the epoxide ring, in which bond angles are constrained to almost half of their normal values. The weakened carbon-carbon and carbon-oxygen bonds in the strained ring structure of ethylene oxide lead to abnormally strong carbon-hydrogen bonds in ethylene oxide, making it unusually difficult for the hydroxyl radical to abstract a hydrogen atom from ethylene oxide. Such abstraction is the usual mechanism for hydroxyl radical attack on volatile organic compounds. The hydrogen abstraction activation energy for ethylene oxide is about twice as high as it is for other ethers (Fritz, 1982). Figure II-6 illustrates the reactions of three epoxides (ethylene oxide, propylene oxide, and butylene oxide) with the hydroxyl radical.

Using electron-spin resonance (esr) spectroscopy, Dobbs (1976) examined free radicals produced from the reactions of epoxides with hydroxyl radicals, which were generated in aqueous solution. The esr spectrograph for the hydroxyl radical-propylene oxide system indicated that only products of hydrogen abstraction from the alkyl group (non-epoxide ring portion of the molecule) were generated. (See Figure II-6, B.) This is consistent with the

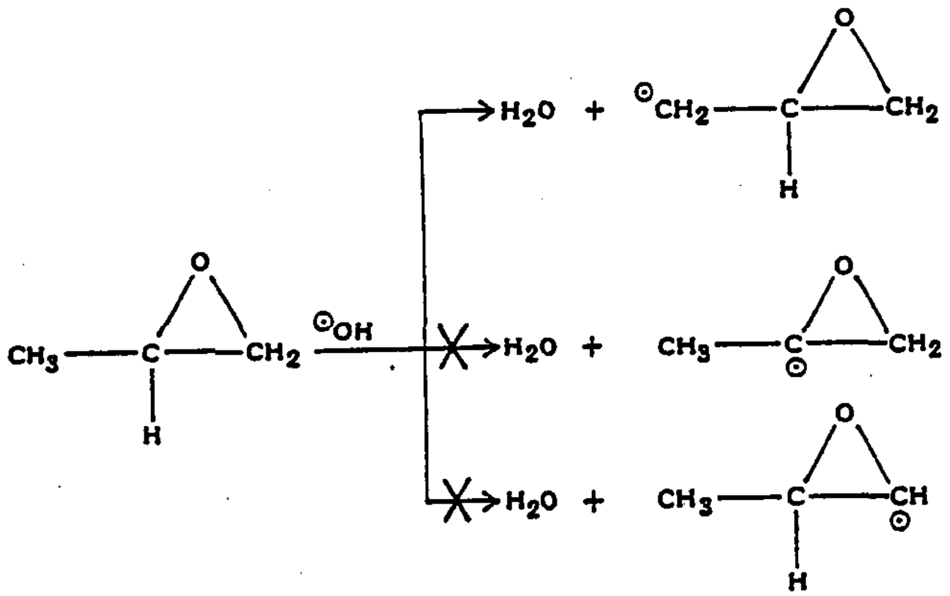
FIGURE II-6

REACTIONS OF EPOXIDES WITH HYDROXYL RADICAL

A) Reaction of ethylene oxide with hydroxyl radical (Dobbs, 1971)

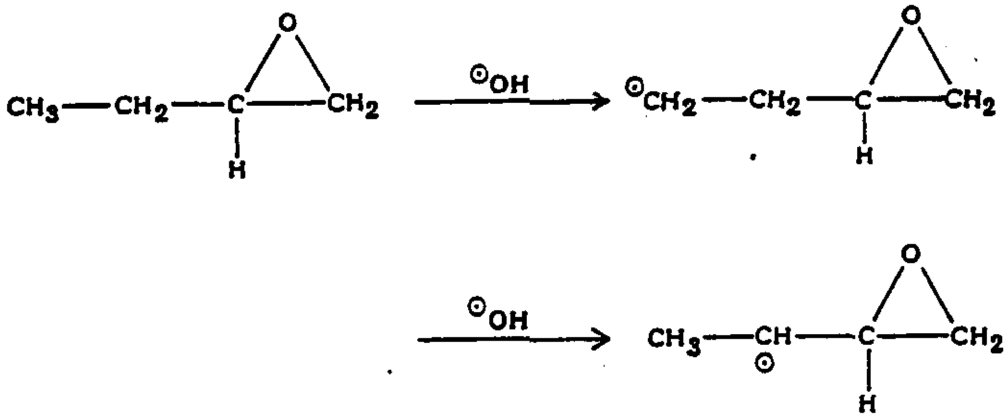


B) Reaction of propylene oxide with hydroxyl radical (Dobbs, 1976)



Hydrogen atom abstraction occurs only
away from the epoxide ring

C) Reaction of butylene oxide with hydroxyl radical (Dobbs, 1971)



Hydrogen atom abstraction occurs only
away from the epoxide ring

prediction of an abnormally strong carbon-hydrogen bond in ethylene oxide, because no hydrogen atom on a carbon atom attached to oxygen was abstracted in propylene oxide. Similarly, butylene oxide yielded radicals only from abstraction of hydrogens from the alkyl group (non-epoxide ring portion of the molecule) (See Figure II-6, C). No hydrogen abstraction from the epoxide ring occurs nor does free radical attack give rise to breakage of the carbon-oxygen bond unless as a result of prior hydrogen abstraction.

Reactions of ethylene oxide with other atmospheric constituents also proceed slowly. EPA (1985a) cited studies showing that the rate of reaction of ethylene oxide with oxygen atoms [$O(^3P)$] is several orders of magnitude slower than that for the hydroxyl radical reaction, and also cited smog chamber studies demonstrating the low reactivity of ethylene oxide with nitrogen dioxide to yield ozone.

ARB staff and California Statewide Air Pollution Research Center (SAPPC) staff agree that "from our understanding of the atmospheric chemistry of organic compounds, we expect that reactions of ethylene oxide with ozone and nitrate radicals will be negligible under atmospheric conditions. Photolysis should also be negligible. The only other processes likely to contribute to the atmospheric removal of ethylene oxide would be wet deposition to surfaces (including to particle surfaces) or hydrolysis" (Winer, 1986a).

2. Reactions with Atmospheric Water

At the request of ARB staff, SAPRC conducted several experiments to determine the rate of hydrolysis of ethylene oxide in humid air. Ethylene oxide concentrations were measured in a polytetrafluoroethylene (PTFE) lined chamber. At approximately 50 percent relative humidity and room temperature, an upper limit loss rate for ethylene oxide is less than or equal to 3×10^{-5} min^{-1}. In fact, no increase in loss rate for ethylene oxide was observed at higher humidity. The upper limit loss rate yields a minimum atmospheric lifetime due to hydrolysis of 23 days, with a likelihood of a much longer lifetime due to this process. With this additional information, SAPRC staff concluded that ethylene oxide will be long-lived in the atmosphere with respect to homogeneous gas-phase processes (Winer, 1986b).

ARB staff and Professor Michael R. Hoffmann of the California Institute of Technology concur that even though water droplets suspended in the air can be acidic, hydrolysis of ethylene oxide is not anticipated to significantly reduce ambient air exposures (Hoffmann, 1987). Based upon experimentally determined hydrolysis rate constants (EPA, 1985a), the following half-lives are calculated for ethylene oxide (in hours at 25°C):

pH	2	3	4	5	6	7	9	11
half-life (hrs.)	2.12	19.9	123	256	287	291	291	116

(Note: half-lives would be longer at lower temperatures, and fog is rare at higher temperatures. For example, at pH = 7 and 20°C, the half-life would be almost twice as long.)

A part of the state with a large population that is subject to frequent acid fog episodes is the South Coast Air Basin. There, fog occurs roughly 15% of the days of the year, and typically persists for less than eight hours per day (Marsh, 1984; U.S. Dept of Commerce, 1944). The pH of these fogs averages above 3, although pH extremes of 1.7 and 7.4 have been encountered.

(Richards, 1985; Hoffmann, 1985)

Although the presence of acidic fog would tend to reduce ambient ethylene oxide concentrations, not enough data are available to quantify the anticipated reduction. However, an upper limit to the effect can be calculated by assuming the fog removes all ethylene oxide in the air. If this were true, then the annual ambient concentrations would be reduced by approximately 5% because fog typically persists no longer than eight hours per day (1/3 day) and occurs roughly 15% of the days of the year.

Ethylene oxide is also eliminated from the atmosphere by physical removal processes such as washout by rain, and adsorption to surfaces. Washout by rain may be less significant than otherwise expected due to the appreciable volatility of ethylene oxide in water solution, as explained in Subsection B. In addition, Dana et al. (1984) measured the ratio of aqueous phase concentration to gas-phase concentration for ethylene oxide at 15°C. (59°F.). Their value for this dimensionless form of the Henry's Law constant is 6.2 (relatively low for water soluble substances), which is consistent with an expectation of a low precipitation scavenging (rain washout) rate.

3. Atmospheric Generation of Ethylene Oxide

ARB staff is unable to estimate ethylene oxide concentrations that might arise from photochemical smog processes or from combustion processes. However, ARB staff and SAPPC staff (Atkinson, 1986) concur that our present understanding of the atmospheric chemistry of organic compounds does not lead to any significant pathways for the atmospheric generation of ethylene oxide. Therefore, although these concentrations are expected to be significantly less than the anticipated ambient levels in urban areas, the above processes could lead to slightly higher ambient ethylene oxide exposures than estimated by emissions modeling only.

Epoxides can be formed in the photochemical smog cycle. Alkenes such as ethylene can react with triplet oxygen atoms [$O(^3P)$] to yield epoxides such as ethylene oxide (Cvetanovic, 1963). This study was done under laboratory conditions with a relatively higher concentration of triplet state oxygen atoms that differs greatly from conditions in the ambient air. Therefore, ARB staff expects that only minor amounts of epoxides are formed in the photochemical smog cycle.

Alkylperoxy radicals can undergo isomerization to yield alkylperoxyalkyl radicals, although this is rarely important. Decomposition of these latter radicals can yield epoxides. However, decomposition is more likely to yield alkenes because of the strain energy involved in formation of epoxides. Furthermore, oxidation probably competes effectively with decomposition (NAS, 1976).

III. SOURCES OF ATMOSPHERIC ETHYLENE OXIDE

Although ethylene oxide is produced in high quantities in the United States, it is not produced in California. The only quantified emissions sources of importance in this state are from ethylene oxide use in sterilization, fumigation, surfactant manufacturing, and from distribution of this compound. Ethylene oxide may also be emitted from combustion of organic materials and from biological processes, but no quantification exists for these sources.

A. PRODUCTION AND USAGE

1. Production

Ethylene oxide is one of the 25 chemicals of highest production volume in the U.S. (Federal Register, 1984). In 1983, approximately 2,767,000 tons of ethylene oxide were produced. Production value grew by 5.4 percent to approximately 2,916,500 tons in 1985 (C&EN, 1986). Growth in ethylene oxide production is projected to continue at an annual rate of about 6 percent from 1984 to 1994 (C&EN, 1985). Currently, ethylene oxide is produced in the United States by 16 facilities, none of which is in California (EPA, 1985a).

From 1974 to 1984, the amount of ethylene oxide imported into the U.S. averaged 5,388 tons, which is less than 0 1 percent of the ethylene oxide available for use in the U.S. An average of one percent of the U.S. ethylene oxide produced from 1974 to 1984 was exported. Figure III-1 shows the total tonnage of ethylene oxide available for use in the U.S. from 1978 to 1985 (C&EN, 1986).

2. Usage

The 1982 national estimates for ethylene oxide use are shown in Figure III-2. Ethylene glycol production is by far the largest use of ethylene oxide

Figure III-1

USE OF ETHYLENE OXIDE IN THE U.S.

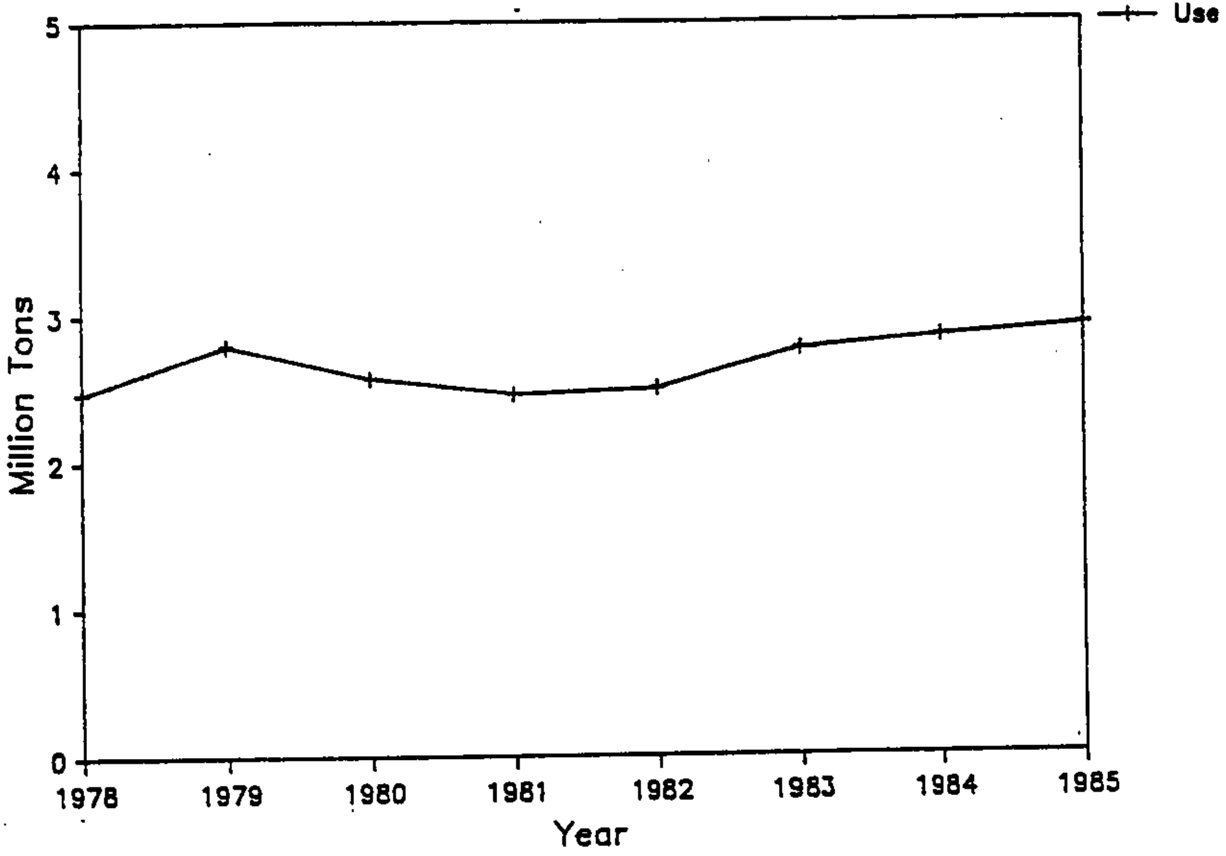
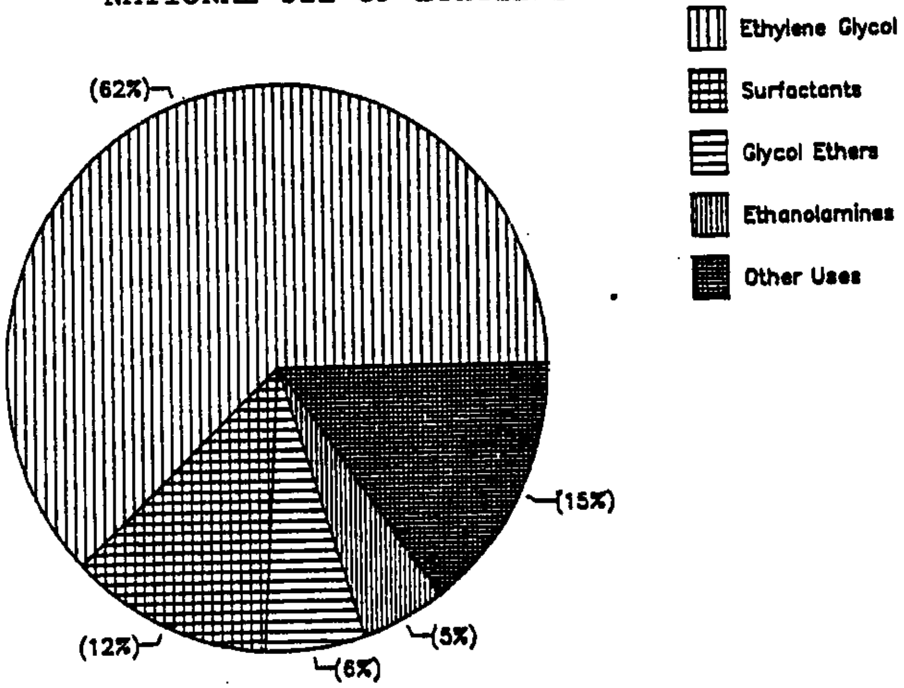


Figure III-2

NATIONAL USE OF ETHYLENE OXIDE



accounting for almost two-thirds of ethylene oxide use. Ethylene glycol is used in automotive antifreeze and polyester production. Other uses include the production of surfactants, the production of glycol ethers used primarily as solvents, the production of ethanolamines used to make soaps and detergent, the production of polyether polyols for flexible polyurethane foams, the production of choline and choline chloride, the manufacture of adhesive additives, sterilization of medical products, and fumigation of food, spices, and other items (EPA, 1985a) (Figure III-2). Of the above uses, only sterilization, fumigation, and surfactant manufacturing are of importance in California. Ethylene glycol, ethylene glycol ether, and ethanolamines are not produced in California.

Although sterilization and fumigation account for less than 0.5 percent of the total U.S. usage of ethylene oxide, these two uses are the major sources of ethylene oxide emissions in California. Hospitals and medical product industries use ethylene oxide to sterilize delicate surgical and optical instruments, plastic and rubber goods, and disposable pre-packaged medical items. It is an effective sterilant for heat- and moisture-sensitive materials which would be destroyed by autoclaving (the principal sterilizing technique used at hospitals).

Ethylene oxide is used as a fumigant to eliminate pest and microbial infestations in food, spices, books, furniture, textiles, empty cargo holds, cosmetics and dairy packaging (Federal Register, 1984). Ethylene oxide is a preferred fumigant for food and spice because of its effectiveness and because it does not alter the flavor of the spices. It increases the shelf-life of refined spices, and prevents the spread of infectious organisms from imported spices.

A potential future use of ethylene oxide is wood treatment. The USDA Forest Product Laboratory has reported that treatment of southern yellow pine with epoxides improved the wood's durability (EPA, 1985a).

B. CURRENT AND PROJECTED ETHYLENE OXIDE EMISSIONS

Ethylene oxide emissions in California are from the following sources:

1) distribution facilities;
2) surfactant manufacturing;
3) sterilization and food/spice fumigation; and
4) other possible sources.

Table III-1 lists ethylene oxide emission estimates for sources in California, categorized by facility type.

1. Distribution Facilities

Fugitive losses of less than 1/2% to 2% of total production occur from storage, handling, drumming and blending of ethylene oxide for use in sterilization (Zwiacher, 1983). Other emissions from distributors result from disposal of residual gas from returned cylinders. ARB staff obtained information from two distributors regarding the percentage of sterilant gas mixture that is exhausted from the cylinders at their repackaging plants. ARB staff used this information to calculate quantities of sterilant gas mixture exhausted from all known ethylene oxide repackaging facilities in California.

In 1985, the five cylinder filling facilities in California disposed of the residual gas evacuated from cylinders in various ways. Two facilities utilized scrubbing or recycling to control emissions to the environment. The other three facilities controlled employee exposure, by methods which transferred the residual gas to the ambient air. One distributor exhausted

TABLE III-1

STATEWIDE ETHYLENE OXIDE EMISSION ESTIMATES BY FACILITY TYPE, 1985

Source	Type of Estimate	Emissions 1/ (ton/year)	Percent 2/ of Total Emissions	Inventory Year	Reference
Distribution Facilities					
Liquid Carbonic					
Los Angeles	Point	2.0	0.6	1985	ARB Sur., 1986
San Carlos	Point	0.7	0.2	1985	ARB Sur., 1986
M.G. Industries	Point	2.9	0.8	1985	ARB Sur., 1986
Union Carbide					
South San Francisco	Point	0.5	0.1	1985	ARB Sur., 1986
Torrance*	Point	0.4	0.1	1985	ARB Sur., 1986
		6.5	1.8%		

* Installation of a more efficient scrubber in 1986 may have lowered emissions.

Source	Type of Estimate	Emissions 1/ (ton/year)	Percent 2/ of Total Emissions	Inventory Year	Reference
Sterilization					
Micro-Biotrol, Inc.	Point	71	19.6	1985	SCAQMD, 1985
Sterilization Services of California	Point	7.3	2.0	1985	SCAQMD, 1987
American Pharmaseal Laboratories	Point	9.5	2.6	1985	SCAQMD, 1987
American Bentley Labs	Point	13	3.6	1985	Zwiacher, 1987
IVAC Corporation	Point	12	3.3	1985	Hellen, 1985
Allergan Pharmaceutical	Point	11	3.0	1982	Zwiacher, 1983
Shiley Labs, Inc.	Point	8.8	2.4	1983	SCAQMD, 1983
Barnes-Hind Pharmaceutical	Point	6.0	1.7	1984	BAAQMD, 1984
Sterile Design, Inc.*	Point	2.7	0.7	1982	Siles, 1982
Abco Laboratories	Point	0.1	0.0	1985/86	EPA, 1987
Medlon, Inc.	Point	2.1	0.6	1985/86	EPA, 1987
Way & Means	Point	2.1	0.6	1985/86	EPA, 1987
3M	Point	0.1	0.0	1985/86	EPA, 1987
American Edwards Lab	Point	2.6	0.7	1985/86	EPA, 1987
Hospitals	Area	63	17.4	1985	ARB Sur., 1986
		210	58%		

* Discontinued operation, December 1985.

Source	Type of Estimate	Emissions[1] (ton/year)	Percent[2] of Total Emissions	Inventory Year	Reference
Fumigation (Food/Spice)					
Cal-Compack Foods, Inc.	Point	25	6.9	1985	Lamb, 1985
Botanicals International, Inc.*	Point	25	6.9	1983	SCAQMD, 1983
McCormick & Co. Inc. (Schilling)	Point	20	5.5	1985	MBUAPCD, 1985
Safeway Spice & Dessert	Point	13	3.6	1984	BAAQMD, 1984
Chili Products Co.	Point	7.0	1.9	1982	Zwiacher, 1983
Foremost Gentry	Point	2.6	0.7	1982	ARB Sur., 1982
Gilroy Foods, Inc.	Point	20.4	5.6	1985/86	EPA, 1987
Santa Maria Chili	Point	10.6	2.9	1985/86	EPA, 1987
Farmer Brothers Co.	Point	1.8	0.5	1985/86	EPA, 1987
		130	34%		

* Process change in 1986 has led to lower emissions.

Source	Type of Estimate	Emissions[1] (ton/year)	Percent[2] of Total Emissions	Inventory Year	Reference
Surfactant Manufacture					
Lonza, Long Beach	Point	12	3.3	1982	Zwiacher, 1983
Emery Industries, Santa Fe Springs	Point	4.3	1.2	1982	Zwiacher, 1983
Tretolite Corp., Brea	Point	3.2	0.9	1982	Zwiacher, 1983
Witco, Carson	Point	1.2	0.3	1982	Zwiacher, 1983
American McGaw Labs., Irvine	Point	0.1	0.0	1982	Zwiacher, 1983
		21	5.7%		
Grand Total		360	100%		

[1] All reported emission estimates have been rounded off by ARB staff to either one-tenth of of a ton/year, or to two significant figures.

[2] Percentages may not add up to 100% due to rounding.

the residual gas from a 40-foot high stack. Two distributors bubbled the gas through water, but most of the resulting dissolved ethylene oxide would be expected to evaporate from the water after discharge (see Section II-A). One distributor had an acid scrubber and one distributor recycled the residual ethylene oxide. Calculated emissions were based on estimated control efficiencies of 90% and 99%, respectively, for facilities that used controls, and from the annual production or emission rates reported by each facility. For a more detailed discussion, see Appendix D.

Total emissions from distributors in 1985, including fugitive losses, are estimated to be about 6.5 tons/year.

2. Surfactant Manufacture

Ethylene oxide is used in California in surfactant (surface-active agent) manufacture. Based on the available information, there are five facilities in the South Coast Air Basin that produce surfactants (Zwiacher, 1983). The SCAQMD estimated facility emissions in 1982 to be one percent of their ethylene oxide usage. Surfactant manufacture ethylene oxide emissions are reported to be about 21 tons/year (Zwiacher, 1983).

According to the EPA (EPA, 1985b), ethylene oxide is usually received at surfactant manufacturing facilities by pressurized railcar, stored, and then reacted with various chemicals in a closed system process. The primary source of ethylene oxide emissions in the ethoxylation process for producing surfactants is assumed to be equipment leaks, although minimal data has been collected. Nationwide, EPA estimates that 1/20 of 1% of the ethylene oxide used by ethoxylators is emitted. Other emissions sources at these facilities are assumed to be negligible.

The EPA has proposed New Source Performance Standards (NSPS) and published Control Technology Guidelines (CTG) for fugitive emissions in the synthetic organic chemistry manufacture industry. Both the NSPS and CTG are applicable to ethoxylator facilities. Implementation of the control techniques specified in the NSPS and CTG would effectively reduce ethylene oxide emissions by approximately 75 and 40 percent respectively (EPA, 1985b).

3. Sterilization/Fumigation

The California Department of Food and Agriculture (DFA) reported that 804,381 pounds of ethylene oxide were sold in California in 1984, and that 957,380 pounds (19% more) were sold in 1985, for commercial gas sterilizers (DFA, 1986).

From a practical standpoint, all the ethylene oxide used in the process of sterilization and fumigation is assumed to be emitted to the atmosphere (EPA, 1985b). Although some ethylene oxide is destroyed on reaction with microorganisms and other materials, this quantity is believed to be a very small percentage of the total quantity used. Figure III-3 provides a flow diagram of an ethylene oxide sterilizer. Emissions from the sterilization or fumigation equipment occur when ethylene oxide is: 1) vented to the atmosphere or discharged into a sewer drain, 2) desorbed from the discharged wastewater[1] (see Section II-B), 3) released through the chamber door of the sterilization/fumigation equipment at the end of a cycle, 4) released from sterilized items during the process of "off-gassing" (again, see Section II-B), and 5) released through leaks in the sterilization equipment.

In March 1986, the ARB conducted a survey of ethylene oxide used by hospitals in the Los Angeles area. The data set for emissions was extrapolated to obtain estimates for the state as a whole. None of the sterilizers had emission control systems other than discharge to wastewater.

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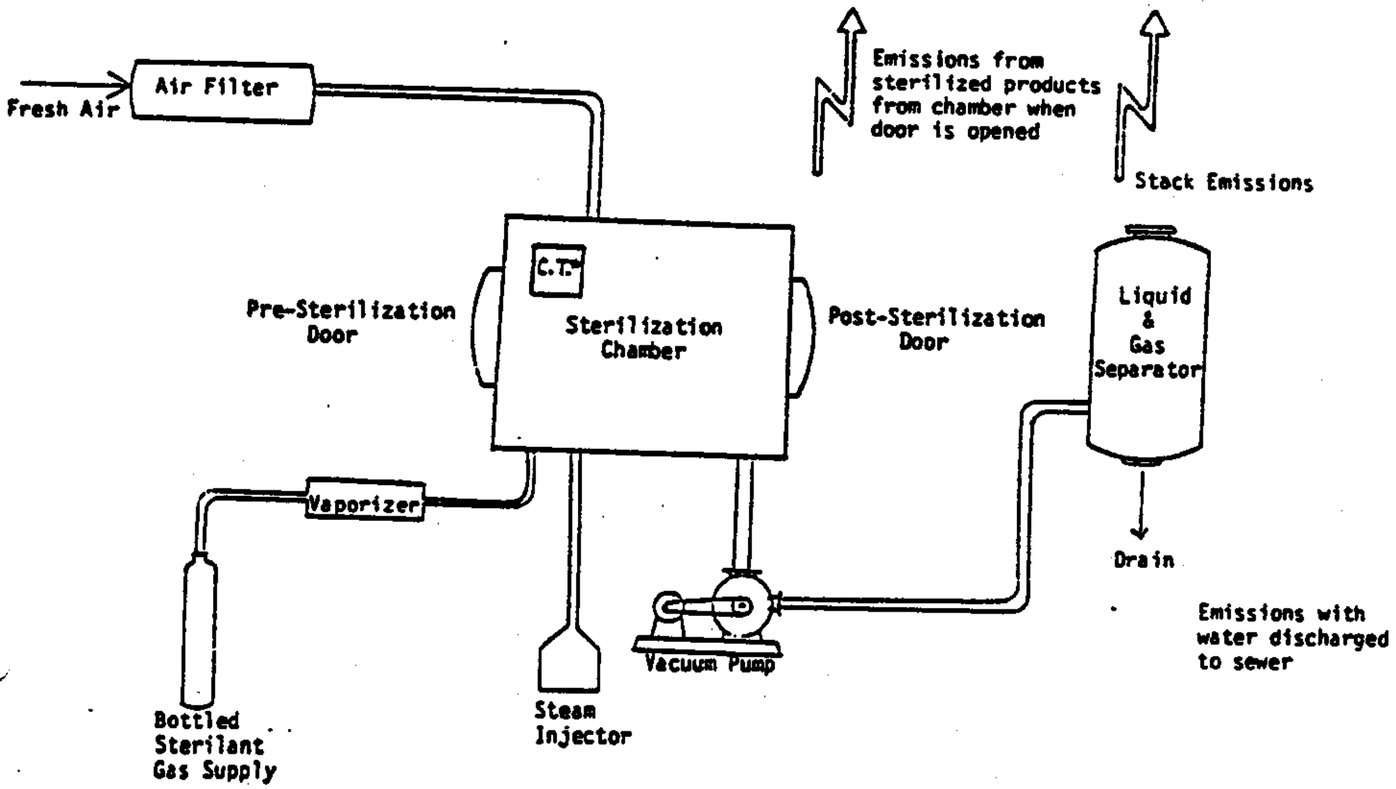
[1] In the absence of low pH or high pH, ethylene oxide discharged to wastewater is eventually released to the atmosphere.

Figure III-3

Flow Diagram of An Ethylene Oxide Sterilizer



* C.T. - Control Panel and Timer

Assuming that all the ethylene oxide used in the process was emitted to the atmosphere, the estimated amount of emissions from all hospitals in California in 1985 is approximately 63 tons/year (see Table III-1). The method used to estimate statewide hospital ethylene oxide usage and emissions based on the 1986 ARB survey is given in Appendix G.

The ARB also surveyed a limited number of industrial sterilizers in 1982 to gather data on large sterilizers. Appendix H gives the method used for estimating ethylene oxide usage and emissions based on the 1982 ARB survey of the medical/pharmaceutical products industry. The estimates of ethylene oxide emissions for these large sterilizers are listed on Table III-1 along with data reported for other large sterilizers to the South Coast Air Quality Management District (SCAQMD) (Zwiacher, 1983). Based on the information available concerning the large sterilizers, only American Pharmaseal, Sterilization Services of California, and Barnes-Hind Parmaceutical, had emissions control devices in 1985. For the other large sterilizers, it is assumed that all the ethylene oxide used in the process for the sterilization of medical and pharmaceutical products was emitted to the atmosphere. For American Pharmaseal, the 1982 emissions were given as 120 tons/year (Zwiacher, 1983). However, in 1984 an incinerator was installed which was believed to have reduced the ethylene oxide emissions from the vacuum exhuast pump such that total emissions of 9.5 tons/year were anticipated (SCAQMD, 1987).

The ARB is not aware of the use in 1985 of any emission control devices for any of the large sterilizers used for food and spice fumigation.

4. Other Possible Sources

EPA allows ethylene oxide to be used in museums, libraries and other areas as a fumigant for miscellaneous items such as books, furniture, textiles, empty bins, empty cargo holds, cosmetic and dairy product containers. No information is available on the quantity of ethylene oxide usage and emissions in California for these sources. Although EPA also allows ethylene oxide to be used to fumigate beehives, the DFA states that ethylene oxide was not used in California in 1985 in the field for any agricultural purpose (Fabre, 1986).

Ethylene oxide has been identified in cigarette smoke, and in the combustion products of hydrocarbon fuels (Hughes, 1959) and n-pentane (Barnard and Lee, 1972). Therefore, ethylene oxide may be a component of stationary and mobile source combustion emissions, although no reliable data base exists for combustion conditions relevant for this report.

Ethylene oxide may also be emitted into the atmosphere as a result of biological processes. DeBont and Albers (1975) have concluded that ethylene oxide is a product of ethylene catabolism by the ethylene-oxidizing E20 bacterium strain.

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APPENDIX A

INFORMATION REQUEST LETTER WITH ATTACHMENTS AND RESPONSES

STATE OF CALIFORNIA GEORGE DEUKMEJIAN, *Governor*

DEPARTMENT OF INDUSTRIAL RELATIONS
DIVISION OF OCCUPATIONAL SAFETY AND HEALTH
5 GOLDEN GATE AVENUE
SAN FRANCISCO

ADDRESS REPLY TO:
P.O. BOX 603
SAN FRANCISCO, CA 94101

November 18, 1985

Mr. William V. Loscutoff, Chief
Toxic Pollutants Branch
California Air Resources Board
P.O. Box 2815
Sacramento, CA 95812

Dear Mr. ~~Loscutoff~~ Bill

Subject: Ethylene Oxide (EtO)

This letter is in response to your request for information on the health effects of ethylene oxide as part of ARB's toxic air contaminant program. As you know, ethylene oxide is regulated as a carcinogen under Cal/OSHA regulations, Title 8, California Administrative Code, General Industry Safety Order Section 5220.

Under this standard, the employer shall ensure that no employee is exposed to an 8-hour time weighted average concentration of airborne EtO in excess of 1 part per million (ppm) of air. The action level is 0.5 ppm. There are many other requirements under this standard, a copy of which is included for your perusal.

Also enclosed for your information is a copy of 29 CFR, Part 1910, Occuptional Exposure to EtO, Final Standard. This is part of the rulemaking package Federal OSHA used to justify their EtO standard and contains useful information on the health effects of EtO. An Information Bulletin on EtO issued by Cal/OSHA is also included for this purpose.

We have had some experience enforcing the EtO standard since March 1985 when it became effective in California. Please call or write this office if we can be of further service to you.

Sincerely,

Frank R. Ciofalo, Ph.D.
Deputy Chief for Health

/jer
encs
cc J. Wong

William V.Loscutoff, Chief
Toxic Pollutants Branch
Re. Ethylene Oxide
California Air Resources Board
P.O. Box 2815
Sacramento,California 95812

Dear Sir;

The first week in November I received a letter from your branch regarding information on Ethylene Oxide.

I am forwarding a copy of the last two surveys for environmental monitoring by Western Medical Technical Services and CAL/OSHA finding no violations of Title and California Administrative Code,GISO 5220.
We have applied and been working with Monterey Bay Unified Air Pollution Control District for a permit to operate. I understand we are to receive the permit. The last inspection was this pass week.

At this point I have a question, do we also have to apply for another type or form of permit to operate from the state branch, or will the Monterey county permit take care of the Air Pollution portion for Health and Safety Code Sections 39650,et seq??

I will be happy to answer the necessary questions for your department if indeed it is necessary.

Thankyou
Dotty A Crosby R.N
Dorothy A. Crosby R.N.
Manager Central Services

November 18, 1985

Whittaker M.A. Bioproducts

Whittaker M.A. Bioproducts, Inc.
P.O. Box 127, Biggs Ford Road
Walkersville, Maryland 21793
Telephone: (301) 898-7025
Toll Free (800) 638-8174
Telex: 6919009MABIO UW

15 November 1985

William V. Loscutoff, Chief
Toxic Pollutants Branch
Re: ETO
California Air Resources Board
P.O. Box 2815
Sacramento, CA 95812

Dear Mr. Loscutoff:

In response to your October 28, 1985 request for information on ethylene oxide, International Diagnostic Technology (former address, 2551 Walsh Avenue, Santa Clara, CA) has been purchased by Whittaker MA Bioproducts, Walkersville, Md. All manufacturing operations will be moved to Maryland. Therefore, we do not feel that we should submit the data that you have requested. If you have any questions, please contact me.

Sincerely,

Patricia B. Shrader
Project Manager

STATE OF NEW HAMPSHIRE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
DIVISION OF PUBLIC HEALTH SERVICES

M. Mary Mongan
Acting Commissioner
Deptartment of Health and Human Services

William T. Wallace, Jr., M.D., M.P.H.
Director
Division of Public Health Services

Health & Welfare Bldg.
6 Hazen Drive
Concord, NH 03301-6527
Tel. (603) 271-

November 15, 1985

William V. Loscutoff, Chief
Toxic Pollutants Branch
Re: Ethylene Oxide
California Air Resources Board
P.O. Box 2815
Sacramento, CA 95812

Dear Mr. Loscutoff:

I have today received the request from Peter D. Venturini for information regarding ethylene oxide. The only technical information in our files which is not listed on your extensive reference list is a N.Y. State Chemical Fact Sheet (enclosed) and pp 654-5 of Handbook of Environmental Data on Organic Chemicals, 2nd Edition by Karel Verschueren.

I hope this information is of vaule.

Sincerely,

John F. Brown

John F. Brown, Ph.D.
State Toxicologist
Division of Public Health Services

JFB/casf
3222s

enc.

cc: Eleanor Robinson, EHRAU

eskaton

good health good living

November 14, 1985

W. V. Loscutoff
Toxic Pollutants Branch
California Air Resources Board
P. O. Box 2815
Sacramento, CA 95812

RE: E.T.O.

Dear Mr. Loscutoff:

Regarding the October 28, 1985 letter from Mr. Venturini requesting input on E.T.O. exhaust from hospitals into the atmosphere, my only comment to this request is that hospitals (small hospitals inparticular) exhaust such small amounts of E.T.O. into the atmosphere that the E.T.O. levels would be impossible to measure.

4 loads per week
.8 lbs. of gas per load
12% E.T.O. per pound of gas
.38 lb. of E.T.O. per week

I would also like to thank you and Mr. Venturini for the excellent bibliography on E.T.O.

Sincerely,

JIM PHILLIPS
Assistant Administrator/
Ancillary and Support Services

JP:sm

MOUNT SHASTA COMMUNITY HOSPITAL • 914 Pine Street • Mount Shasta, California 96067 • 916/926-6111

Los Robles Regional Medical Center

215 West Janss Road
Thousand Oaks, CA 91360
Tel (805) 497-2727

Robert L. Quist
Administrator

November 15, 1985

Mr. William V. Loscutoff
Chief Toxic Pollutants Branch
Re: Ethylene Oxide
California Air Resources Board
P. O. Box 2815
Sacramento, California 95812

Dear Mr. Loscutoff:

This is a response to your request for information regarding Ethylene Oxide. Fortunately, Los Robles Regional Medical Center has not experienced any unusual occurrences with regard to the use of Ethylene Oxide in our Central Service Department. Our Employee Health Nurse has not received any reports of ill effects regarding the use of Ethylene Oxide.

I hope this information will be very helpful to you. Should you need additional information, please contact me at your convenience.

Very truly yours,

Marty Hodges

Marty Hodges, RN
Quality Assurance/
Risk Management Coordinator

MH:jk

cc: H. Hurtado, Central Service Supervisor
J. Chang, Safety Chairperson/Employee Health Nurse
R. Quist, Administrator

HCA Hospital Corporation of America

MSD ISOTOPES

MERCK SHARP & DOHME/ISOTOPES
DIVISION OF MERCK FROSST CANADA INC., Montreal, Canada

November 29, 1985

Mr. W. V. Loscutoff,
California Air Resources Board,
P.O. Box 2815,
Sacramento, CA 95812

Subject: Toxic Pollutants - Ethylene Oxide.

Gentlemen:

I respond to your correspondence of October 28th last regarding your ARB investigation of Ethylene Oxide.

Our laboratories do work with Ethylene Oxide as a laboratory chemical, and prepare various stable (NON-radioactive) isotope-labelled forms for use by researchers as part of our day-to-day production of our chemicals. These unique labelled chemicals are sold in mg-gram quantities to research laboratories equipped with nuclear magnetic resonance and/or mass spectroscopy instrumentation.

We are a chemicals' synthesis operation, and as such , do no application or health effects studies. Where such information is required (for our staff protection, for Material Safety Data Sheets, etc.), we too rely on the published technical literature.

We therefore regret that we do not have any new or proprietary data to submit to your review panel.

Would it be possible to send us a list of compounds identified by your Board as toxic air contaminants? If so, please direct it to the undersigned.

Sincerely,

Maureen Kalloo
Manager, Sales Service,
MSD Isotopes.

P.O. Box 899, Pointe Claire - Dorval, Quebec, Canada H9R 4P7 - Tel 514-697-2823 - Telex 05-821-533 - Cable: ISOMERCK

METROPOLITAN DADE COUNTY, FLORIDA

METRO·DADE

ENVIRONMENTAL RESOURCES MANAGEMENT
SUITE 1310
111 N.W. 1ST STREET
MIAMI, FLORIDA 33128-1971
(305) 375-3376

November 18, 1985

William V. Loscutoff, Chief
Toxic Pollutants Branch
Re: Ethylene Oxide
California Air Resources Board
P.O. Box 2815
Sacramento, CA 95812

Dear Mr. Loscutoff:

Although I do not have additional information regarding the health effects of ethylene oxide, I would like to continue to receive information inquiries for other ARB candidate substances.

Sincerely,

Carl D. Pfaffenberger

Carl D. Pfaffenberger, Ph.D.
Chief, Environmental Planning
Division

CP:lbf

November 25, 1985

William Loscutoff, Chief
Toxic Pollutants Branch
Re: Ethylene Oxide
California Air Resources Board
P. O. Box 2815
Sacramento, CA 95812

Dear Mr. Loscutoff:

Thank you for your recent letter requesting information on ethylene oxide.

Redken Laboratories does not use ethylene oxide at our Canoga Park manufacturing site. Therefore, we unfortunately do not have any other information on the health effects of ethylene oxide.

If you have any other questions about this matter, please feel free to write to me.

Sincerely,

Ron Kvaas

Ronald A. Kvaas
Director Technical Services
and Compliance
REDKEN LABORATORIES

RAK:gcb

CLEARY, GOTTLIEB, STEEN & HAMILTON
1752 N STREET, N. W.
WASHINGTON, D. C. 20036
202 728-2700
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PRINTING HOUSE
18 ICE HOUSE STREET
HONG KONG

December 2, 1985

Mr. William V. Loscutoff, Chief
Toxic Pollutants Branch
Re: Ethylene Oxide
California Air Resources Board
P. O. Box 2815
Sacramento, California 95812

Dear Mr. Loscutoff:

As Chairman of the Scientific Committee of the Ethylene Oxide Industry Council ("EOIC"), I am submitting herewith information regarding ethylene oxide ("EO") in response to a letter dated October 28, 1985, from Mr. Peter D. Venturini. The specific items being submitted are described below.

For your background information, the EOIC is a special program of the Chemical Manufacturers Association representing both producers and users of EO. The membership of the EOIC accounts for over 90 percent of domestic production of EO and includes ethoxylators and a broad spectrum of companies (other than hospitals) that use EO as a sterilant for medical supplies and food products. The EOIC is principally involved in the development and communication of scientific information relating to EO.

Description of Information Submitted

1. Comprehensive Hazard Assessment

Dr. Leon Golberg, Professor of Community/Occupational Medicine, Duke University Medical Center, has prepared a comprehensive hazard assessment of EO, as a consultant to the EOIC. In the Hazard Assessment, Dr. Golberg discusses the relevant qualitative and quantitative information regarding EO, and characterizes the hazards associated with exposure to EO, using three quantitative zones of time-weighted exposure. The Golberg Hazard Assessment is being published by CRC Reviews. The enclosed document is an April 1984 draft that has been submitted to EPA in connection with its draft Health Assessment Document for EO. Dr. Golberg's Hazard Assessment has since undergone additional peer-review and is now undergoing final preparations for publication. We expect to receive permission from CRC to submit a copy of the revised Hazard Assessment, and we will send it to you once permission is received and a prepublication or published version is available. Also enclosed in connection with Dr. Golberg's Hazard Assessment are peer review comments by Dr. Robert A. Squire and Dr. Joseph Grisham, who reviewed the enclosed version of the Hazard Assessment. Enclosed in addition are a report by Dr. Robert L. Sielken, Jr. on the statistical extrapolation in the EPA HAD and a sensitivity analysis by Dr. Sielken of important assumptions in the EPA extrapolation.

2. Reproductive Effects

The EOIC has prepared a significant amount of information regarding the report by Hemminki et al. of reproductive effects in sterilant workers exposed to EO. Enclosed are: (a) an EOIC Assessment Report on the Hemminki study; (b) a Trip Report of an EOIC visit with Dr. Hemminki (the handwritten original of which was signed by Dr. Hemminki); (c) correspondence in the British Medical Journal regarding the Hemminki study; and (d) peer review comments on the Hemminki study. Also enclosed are a report by Dr. Susan Austin on reproductive epidemiology regarding EO and a submission to OSHA by Dr. William M. Snellings regarding the one-generation reproduction and teratology studies on rats conducted at Bushy Run Research Center.

3. Human Mortality Studies

Enclosed are copies of mortality studies by Morgan et al. and Thiess et al. that were not included in the bibliography attached to Mr. Venturini's letter. Also attached is a report by Dr. Robert Morgan on the human mortality studies.

4. Cytogenetic Effects

Enclosed are unpublished reports by Dr. Julian Preston, Oak Ridge National Laboratory, regarding the use of cytogenetic data to assess risk or to monitor exposed populations.

5. Science Advisory Board Letter

Enclosed is a letter from the EPA Science Advisory Board (SAB) to the EPA Administrator, setting forth the SAB's comments on EPA's draft health assessment document for EO.

6. EOIC Comments

Enclosed are comments that the EOIC is submitting to the United States Environmental Protection Agency in response to that agency's notice of intent to list EO as a hazardous air pollutant under section 112 of the Clean Air Act.

Please do not hesitate to let me know if I can be of any further assistance in this matter.

Very truly yours,

Norm Gaines

Norman W. Gaines
Chairman, Scientific Committee

cc: Mr. Richard L. Davis (w/enc.)
Chemical Industry Council
of California

cma
CALIFORNIA MEDICAL ASSOCIATION
44 Gough Street • San Francisco, California 94103-1233 • (415) 863-5522

December 6, 1985

William V. Loscutoff, Chief
Toxic Polluntants Branch
RE: Ethylene Oxide
California Air Resources Board
P.O. Box 2815
Sacramento, CA 95812

Dear Mr. Loscutoff:

When I received your request for information regarding ethylene oxide, I forwarded it on to my Committee on Environmental Health as well as my Committee on Occupational Health for their review. Both Chairmen put it on their meeting agendas to be discussed.

The committee members were very interested in the Air Resources Board's toxic air contaminant program and would like to be kept apprised of your progress; however, they didn't feel they had the expertise to add any input and so declined commenting on ethylene oxide.

Please be sure the California Medical Association is on your mailing list for future requests and I will continue to send them on to the appropriate committees.

Sincerely,

Catherine L. Maley

Catherine L. Maley
Staff Coordinator
Community Health Services

cc: Martin J. Gavin, Jr., M.D.
Rebecca Craig

U.S. ARMY ENVIRONMENTAL HYGIENE AGENCY
Industrial Hygiene Division
Aberdeen Proving Ground, Maryland 21010-5422

January 3, 1986

SUBJECT: Ethylene Oxide California Air Resources Board

William V. Loscutoff
Chief Toxic Pollutants Branch
P. O. Box 2815
Sacramento, California 95812

Dear Mr. Loscutoff:

Reference your letter dated October 28, 1985, subject: Request for Information Regarding Ethylene Oxide.

I am not aware of any information concerning adverse health effects of ethylene oxide that is more current than the citations listed in the attachment to the referenced letter.

Please send me a copy of your final report on the health effects of ethylene oxide when it becomes available. My address is: Commander, U. S. Army Environmental Hygiene Agency, ATTN: HSHB-OI-S/CPT Caldwell, Aberdeen Proving Ground, MD 21010-5422.

Sincerely,

D Caldwell

Daniel J. Caldwell
Captain, Medical Service
Corps
Hospital Industrial
Hygienist

PACIFIC GAS AND ELECTRIC COMPANY

[illegible] 77 BEALE STREET • SAN FRANCISCO, CALIFORNIA 94106 • (415) 781-42[illegible] • TWX 910-372-6587

June 4, 1986

Mr. William V. Loscutoff, Chief
Toxic Pollutants Branch
Re: Ethylene Oxide
California Air Resources Board
P.O. Box 2815
Sacramento, California 95812

Dear Mr. Loscutoff:

Request for Public Health
<u>Information Regarding Ethylene Oxide</u>

Pacific Gas and Electric Company received your October 28, 1985 request for additional public health information regarding Ethylene Oxide. We have reviewed the bibliography attached to your request and concluded that we are unaware of any additional information which would be of use to you.

When the risk assessment report becomes available, please send me a copy.

Sincerely,

J. F. McKenzie

APPENDIX B

HEALTH EFFECTS REQUEST TO DHS AND LETTER OF RESPONSE

e of California

Memorandum

To : Kenneth Kizer, M.D., Director
Dept. of Health Services
714 P Street
Sacramento, CA 95814

Date : December 26, 1985

Subject: Evaluation of
Ethylene Oxide

James D. Boyd
Executive Officer
From : Air Resources Board

I am writing to formally request that the Department evaluate the health effects of ethylene oxide as a candidate toxic air contaminant in accordance with Assembly Bill 1807 (Tanner). According to Health and Safety Code Sections 39660-62, your Department has ninety days to submit a written evaluation and recommendations on the health effects of ethylene oxide to the Air Resources Board. If necessary, the Department may request a thirty-day extension. Attached for your staff's consideration in evaluating ethylene oxide are: Attachment I - a list of references on ethylene oxide health effects which were identified in an ARB letter of public inquiry; Attachment II - a supplemental list of references provided by the public in response to the ARB inquiry letter; and Attachment III - estimated ambient ethylene oxide concentrations which should be used to estimate the range of risk to California residents as required in Health and Safety Code Section 39660(c).

My staff is available for consultation in conducting this health effects evaluation. We look forward to continuing to work closely with you and your staff in carrying out this legislative mandate. If you have any further questions regarding this matter, please contact me at 445-4383 or have your staff contact Peter D. Venturini, Chief of the Stationary Source Division, at 445-0650.

Attachments

cc: Jananne Sharpless
Alex Kelter, DHS, w/attachments
Raymond Neutra, DHS, w/attachments
Peter D. Venturini, ARB
Assemblywoman Sally Tanner
Clare Berryhill, DFA
Emil Mrak, Chairman and member of the Scientific Review Panel
Senator Ralph Dills
Senator Art Torres
John Holmes, ARB

ATTACHMENT I

References on Ethylene Oxide Health Effects Prepared by the Air Resources Board.

STATE OF CALIFORNIA GEORGE DEUKMEJIAN, *Governor*

RESOURCES BOARD
Q STREET
P.O. BOX 2815
SACRAMENTO, CA 95812

October 28, 1985

Dear Sir or Madam:

<u>Request for Information Regarding Ethylene Oxide</u>

I am writing to request information on the health effects of ethylene oxide as part of our toxic air contaminant program. This program is based on Health and Safety Code Sections 39650, <u>et seq</u>. which requires the Air Resources Board (ARB) to prepare a report which would serve as the basis for regulatory action and to determine by regulation, whether a substance is a toxic air contaminant. Once identified as a toxic air contaminant, the law further requires that the ARB prepare a report on the need and appropriate degree of regulation for the substance. After consultation with the staff of the Department of Health Services (DHS), we have selected ethylene oxide as a candidate toxic air contaminant to be evaluated in accordance with the provisions of Health and Safety Code Sections 39650, <u>et seq</u>. During our evaluation of ethylene oxide, we will consider all available health information regarding this substance. Additionally, we are soliciting information regarding possible biological transformations of ethylene oxide.

Before the ARB can formally identify a substance as a toxic air contaminant, several steps must be taken. First, the ARB must request the Department of Health Services to evaluate the health effects of the candidate substance. Second, the ARB staff must prepare a report which includes the health effects evaluation and then submit the report to a Scientific Review Panel for its review. The report submitted to the Panel will be made available to the public. Information submitted in response to this request will be considered in the report to the Panel. Although any person may also submit information directly to the Panel for its consideration, I urge you to submit all information at this time for our consideration in the development of the report for the Panel. The Panel reviews the sufficiency of the information, methods, and data used by the DHS in its evaluation. Last, after review by the Scientific Review Panel, the report with the written findings of the Panel will be considered by the Air Resources Board and will be the basis for any regulatory action by the Board officially to identify a substance as a toxic air contaminant.

Prior to formally requesting the DHS to prepare a health effects evaluation of ethylene oxide, we are providing, pursuant to the provisions of Section 39660(e) of the Health and Safety Code, an opportunity for interested parties to submit information on the health effects of ethylene oxide which he or she believes would be important in DHS' evaluation of ethylene oxide as a candidate toxic air contaminant.

In July 1985, we received a reference search on ethylene oxide health effects using the MEDLINE, TOXLINE, and BIOSIS data bases available from the National Library of Medicine and/or Dialog information services. These information services include material published from 1965 to mid-1985. The attached bibliography lists the references from this information search. We are requesting pertinent information on ethylene oxide health effects, including any material that may not be available to the public and/or that is not included in the attached bibliography.

Pursuant to the provisions of the Public Records Act (Government Code Sections 6280 et seq.), the information you provide will be public record and subject to public disclosure, except for trade secrets which are not emission data or other information which is exempt from disclosure or the disclosure of which is prohibited by law. The information may also be released to the Environmental Protection Agency, which protects trade secrets and confidential information in accordance with federal law, and to other public agencies, which are also required to protect such information.

To expedite the review process, we ask that any information which you believe should be regarded as "trade secret" be clearly marked and separated from other information. You may identify portions of the information you submit as "trade secret" in accordance with Health and Safety Code Section 39660(e). The claim of trade secrecy must be supported upon the request of the Air Resources Board. Other information claimed to be trade secret and information otherwise claimed to be exempt from disclosure may be identified as confidential in accordance with Section 91011, Title 17, California Administrative Code. Section 91011 requires that the claim of confidentiality be accompanied by specified supporting information.

I would appreciate receiving any relevant information you wish to submit by December 2, 1985. Your help in expediting our review will be greatly appreciated. Please send the information to the attention of:

William V. Loscutoff, Chief
Toxic Pollutants Branch
Re: Ethylene Oxide
California Air Resources Board
P. O. Box 2815
Sacramento, CA 95812

If you have any further questions regarding health effects information, please contact Mr. John Batchelder at (916) 323-1505. For any other questions, please contact Mr. Robert Barham at (916) 322-7072.

If you are not the person to whom this request should be addressed, please forward it to the appropriate person in your organization. Also, please let us know whether you would like to continue to receive information inquiries for other candidate substances, and if not, if there is anyone in your organization to whom such requests should be sent.

Sincerely,

Peter D. Venturini, Chief
Stationary Source Division

Attachment

cc: Alex Kelter, DHS
Lori Johnston, DFA
Wayne Morgan, President, CAPCOA
Jan Bush, Executive Secretary, CAPCOA
David Howekamp, EPA Region IX
Assemblywoman Sally Tanner, Chairwoman, Committee on Toxic Materials
Senator Ralph Dills, Chairman, Committee on Governmental Organization
Senator Art Torres, Chairman, Committee on Toxics and Public Safety Management
Emil Mrak, Chairman, and Scientific Review Panel Members
APCOs

References for The Health Effects of Ethylene Oxide (10/10/1985)

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2) Anon \Toxicity of ethylene oxide and its relevance to man, \European Chemical Industry, Ecology and Toxicology Centre, Avenue Louise 250, Bo:ite 63, 1050 Bruxelles, Belgium, 20 Sep. 1982. 75p. Illus. 146 ref.

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California State University, Sacramento
6000 J STREET, SACRAMENTO, CALIFORNIA 95819-2694

October 31, 1985

Mr. Peter D. Venturini, Chief
Stationary Source Division
Air Resources Board
P. O. Box 2815
Sacramento, CA 95812

Dear Mr. Venturini:

I am referring your request of October 28th to Dr. Arnold Golub, Director of Research and Sponsored Programs. Dr. Golub is the person that should receive further requests of this kind.

Sincerely,

June Stuckey

June E. Stuckey
Associate Vice President
Program Development and Evaluation

JES/cb

cc: Dr. Golub

THE CALIFORNIA STATE UNIVERSITY

VWR Scientific
division of [illegible]

P.O. BOX 7900
SAN FRANCISCO, CA 94120
PHONE (415) 468-7150

October 31, 1985

Mr. William V. Loscutoff, Chief
Toxic Pollutants Branch
Re: Ethylene Oxide
California Air Resources Board
P.O. Box 2815
Sacramento, Calif. 95812

Dear Mr. Loscuttoff:

With this note we acknowledge the receipt of your letter entitled: Request for Information Regarding Ethylene Oxide.

We do not distribute this product, are not manufacturers and do not, to the best of our knowledge, have any experience regarding the product and its effects.

Very truly yours,

Sheldon B. Cameron

Sheldon B. Cameron
Marketing Services Manager

SBC:gr

VWR—People Dedicated To Excellence In Distribution.

BARNES-HIND INC.
A Revlon Vision Care Company

1 November, 1985

Mr. William V. Loscutoff, Chief
Toxic Pollutants Branch
California Air Resources Board
P.O. Box 2815
Sacramento, CA 95812

Dear Mr. Loscutoff:

Re: Ethylene Oxide

This is in response of your request for information concerning health effects of Ethylene Oxide.

Barnes-Hind is a DOHS registered user of Ethylene Oxide only. It is used as a sterilant gas as part of our production process of pharmaceutical and consumer ophthalmic solutions. We have no additional data or information to submit to the ARB regarding the health effects of Ethylene Oxide.

However, we would appreciate being kept apprised of ongoing developments, notice of intended rule changes, regulatory actions, etc. vis-a-vis Ethylene Oxide emissions. Thank you.

Very truly yours,

Joseph Bernosky

/Joeseph J. Bernosky, Jr.
Manager, Safety and Environmental Affairs

JJB:dpc

cc: D. Hanson

RECEIVED

NOV 6 1985

Stationary Source
Division
Air Resources Board

November 4, 1985

Peter D. Venturini, Chief
Stationary Sources Division
Air Resources Board
1102 Q Street
P.O.BOX 2815
Sacramento, Ca. 95812

Dear Mr. Venturini:

Thank you for the Reference for the Effects of Ethylene Oxide (10-10-85). At this time we have nothing to contribute to the review.

Any further communication should be addressed to me.

Cordially,

Virginia Espy
Director of Central Services

VE:ns

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Attachment III
Estimated Ambient Ethylene Oxide Concentrations

Although ethylene oxide (EtO) is not manufactured in California, it is estimated that between five and ten million pounds are imported for California use annually. EtO use is expected to stay at current levels in the near future. More than 90% of ethylene oxide emissions statewide are from sterilization of medical products and fumigation of spices and other foodstuffs.

EtO has not been detected in the ambient air and the detection limit (approximately 200 micrograms per cubic meter) is above the estimated maximum concentration downwind of a major source. At one industrial source, the Schillings Company facility in Salinas, California, the Air Resources Board (ARB) conducted an emission source test and modeled the dispersion plume to estimate the maximum ambient concentrations to which the public might be exposed. The maximum annual average ground level concentration from this source was estimated to be 38.5 micrograms per cubic meter (21.4 ppb) above the ambient level. Although the ambient level has not been measured, it can be assumed to be zero for the risk calculations.

The Schillings facility emits an estimated 17 tons of EtO per year. The ARB is aware of a facility in the South Coast Air Basin that is estimated to emit 120 tons/year of EtO, or about seven times as much as the Schillings facility. Therefore, for the purpose of risk assessment, concentrations up to 270 micrograms per cubic meter (150 ppb) should be considered.

Numerically, hospitals represent the largest category of emission sources of ethylene oxide in California. A typical large city hospital uses roughly 2.5 tons/year of ethylene oxide. Assuming 100% of the EtO used is emitted, a maximum annual ground level concentration from such a source is estimated to be about 16.5 micrograms per cubic meter (9 ppb) above the ambient level.

State of California

Memorandum

To : Michael Lipsett, M.D., J.D.
Department of Health Services
2151 Berkeley Way
Berkeley, CA 94704

Date : January 2, 1986

Subject : Ethylene Oxide

Gary Murchison, Manager
Compound Evaluation Section
From : Air Resources Board

On December 26, 1985, the Air Resources Board (ARB) formally requested that the Department of Health Services (DHS) evaluate the health effects of ethylene oxide as a candidate toxic air contaminant. Attachment II of that request was a list of references on health effects that were provided to ARB by the public. In most cases, copies of the reference material were also provided to the ARB. In the past we have normally provided DHS with copies of all the material we receive; however, this time, the amount of material was so large we have asked two of the submitters to mail copies of their references directly to you. Both submitters have recently agreed to this, and you should therefore be receiving material from Cleary, Gottlieb, Steen and Hamilton, as well as from Cal/OSHA within the week.

Photocopies of all other health related material sent to us are enclosed. They are from the New York State Department of Environmental Conservation, the Hemet Valley Hospital District, the State of New Hampshire Division of Public Health Services, and the Los Robles Regional Medical Center.

If you have not received the material from Cleary or Cal/OSHA by January 10, 1986, please contact Ralph Propper of my staff at 8-492-8284 and he will provide you with the necessary material.

Enclosure

APR 10 1986
Department of Health Services

State of California

Memorandum

To : James Boyd
Executive Director
California Air Resources Board
1102 Q Street
Sacramento
B-4

Date :

Subject: Request for Extension of Ethylene Oxide Evaluation

From : Office of the Director
714 P Street, Room 1253
Sacramento
5-1248

The Department of Health Services will be unable to complete the AB1807 document on ethylene oxide by the current deadline and is thus requesting the statutory 30-day extension plus an additional 30 days to May 25, 1986.

John Ramey
for Kenneth W. Kizer, M.D., M.P.H.
Director

OCT - 2 1986

State of California **Department of Health Services**

Memorandum

To : James D. Boyd
Executive Office
Air Resources Board
P.O. Box 1253
B-4

Date : September 30, 1986

Subject: Health Effects of Ethylene Oxide

RECEIVED

Stationary Source
Division
Air Resources Board

From : Office of the Director
714 P Street, Room 1253
5-1248

Attached is the document prepared in response to your request for the assistance of the Department of Health Services in evaluating the health effects of ethylene oxide as a potential toxic air contaminant.

Kenneth W. Kizer, M.D., M.P.H.
Director

Attachment

cc: C. Berryhill, Director of Food & Agriculture
J. Sharpless, Chairwoman, Air Resources Board
Assemblywoman Tanner, State Capitol
P. Venturini, Chief, Stationary Sources Division

Copies of the document can be requested from:

California Department of Health Services
Epidemiological Studies and Surveillance Section
2151 Berkeley Way, Room 515
Berkeley, CA 94704

APPENDIX C

SOUTH COAST AREA MODELING METHODS AND RESULTS

SOUTH COAST AREA MODELING METHODS AND RESULTS

The information in this section provides a detailed description of the methods used to obtain the exposure estimates presented in Section I-A of the report.

The ARB staff decided to perform area-wide emission modeling, in order to determine the cumulative impact resulting from a combination of ethylene oxide emission sources. This analysis provided exposure data which was used to estimate the aggregate increased health risk attributable to ethylene oxide.

I. METHODS TO DETERMINE EMISSIONS

An area of the South Coast Air Basin was chosen for air quality modeling because it has a large population and a relatively high population density, and because it has many hospital sterilizers and a few large industrial sources of ethylene oxide. All the hospitals and industrial facilities that were known to use ethylene oxide were included, if they lay within an inventory area bounded generally by: on the north, the Santa Monica Mountains, including southern Glendale and Pasadena; on the south, Rosecrans Ave.; on the west, Pacific Palisades southward to the Pacific Ocean; on the east, Bloomfield Ave. northward to Rosemead Blvd. and Temple City Blvd.

The inventory area was bounded by the following UTM (Universal Transverse Mercator) coordinates: S-3749, N-3778, E-399, W-362. These were chosen by balancing the desire to include a large number of emission sources in a dense population area, with the technical limitations and costs of modeling an extensive area.

ARB staff selected all acute-care hospitals which were located in the inventory area from the "Health Facilities Directory" published by the Department of Health Services in July 1985. To complete the list, staff also consulted "A Guide to the Health Care Field" published by the American Hospital Association in 1985. The locations of all these hospitals were plotted on topographic maps. The inventory area encompassed 71 hospitals, including one with two locations. The inventory area also included one large industrial user of ethylene oxide and two ethylene oxide gas repackaging facilities.

ARB staff contacted each hospital in the inventory area by telephone during March, 1986. Information solicited included number and sizes of sterilizers in use, frequency of sterilizer use, pounds of gas used per load, time of day of emissions, and height above ground of emissions.

Of the 72 hospital locations originally identified, four were closed at the time of the survey and 13 reported that no ethylene oxide sterilizers were used at that facility. Of the 55 that acknowledged use of ethylene oxide, approximately half of the respondents did not know how many pounds of gas their sterilizers used per load. In these cases the amount of gas purchased over a period of time was accepted as an alternate means of calculating emissions.

Emission rates were calculated by multiplying loads per week by pounds per load and multiplying by 12% if the sterilant gas mix consisting of 12% ethylene oxide were used. If the amount of gas purchased per month was given, the number of pounds of gas was divided by the appropriate number of loads per month and multiplied by 12% if sterilant gas mix were used. Because most hospitals did not operate their sterilizers seven days per week a calculation of pounds of ethylene oxide emitted per week was divided by seven to obtain daily emissions. Many hospitals did not follow an operating schedule but operated their sterilizers as needed. For hospitals which reported a range of hours over which ethylene oxide might be released, the average was designated as the time of release.

Respondents reported that some of the gas purchased was returned to the distributors. There were two reasons for this. First, when the pressure in the cylinder no longer delivers gas to the sterilizer chamber at a sufficient rate to appropriately pressurize the chamber, the cylinder is changed. The pressure at which the cylinder is changed varies from hospital to hospital. Some hospitals remove it at as low as 20 psi gauge pressure, while others remove it at as high as 50 psi. Second, the product has a limited shelf-life due to a catalyzed polymerization reaction. Therefore, some facilities employ a pull-date system which can result in unused gas being returned to the distributor.

To arrive at a reasonable correction for residual gas not released at the hospitals, staff reviewed the data and noted that data on both pounds per load, as well as pounds purchased in a time period and number of loads for that time period, were available for 15% of the hospitals. Calculations showed the percentage of cylinder gas returned ranged from 7% - 47%, and averaged 23%. Staff elected to use a 20% reduction factor for emissions from hospitals where only the amount of gas purchased was given. An estimate was entered for the single hospital that still had not provided specific information at the conclusion of the project. The estimate used for this source was derived by correlating ethylene oxide use with number of beds, obtained from the survey results.

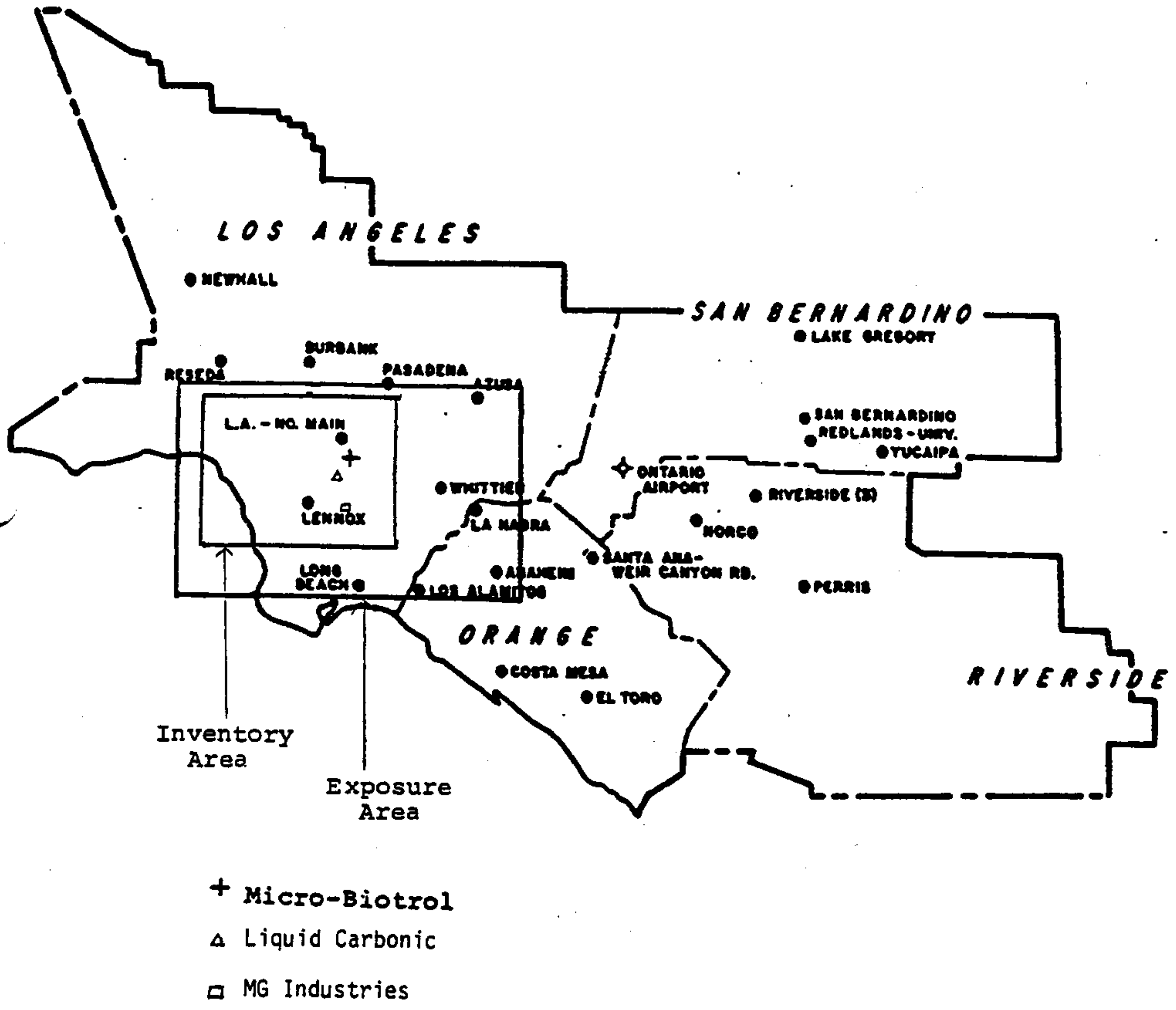
Due to limitations in modeling capability and lack of data, the following simplifications and assumptions were employed. It was assumed that all the ethylene oxide used in a load is emitted in the hour during which the sterilizer is purged and weekly ethylene oxide emissions occurred at the stated time seven days per week. Normalizing weekly emissions over seven days would not yield an estimate of maximal impact, but would adequately characterize cumulative impact. The assumption that all the ethylene oxide used in a sterilizer is emitted during purging of the sterilizer chamber neglects several factors. Some ethylene oxide will be dissolved in the water used to seal the vacuum pump and some will be absorbed in the sterilized articles. Initially this might be as much as 12.5% of the ethylene oxide used. However, much of the ethylene oxide associated with the product will be desorbed and emitted in the subsequent aeration phase (lasting 6 to 12 hours after the purge), and much of the ethylene oxide dissolved in the water will revolatilize (see section on ethylene oxide properties in main report). Therefore, hospital ethylene oxide usage per load was translated into total ethylene oxide emissions per load and can be considered an upper limit to emissions.

II. MODELING METHODS

ARB modeled the dispersion of ethylene oxide emissions from the sources located within the inventory area in the South Coast Air Basin. A somewhat larger exposure area was used to model potential exposures from the inventory area (Figure C-1). Out of a total of 58 sources modeled, 55 were hospitals and three were industrial. Ethylene oxide is used in sterilization processes by all but two of the 58 sources: Liquid Carbonic Corp., and MG Industries. These two sources are distributors of ethylene oxide, with most of their ethylene oxide emissions attributed to purging of returned ethylene oxide cylinders. The largest source of ethylene oxide is Micro-Biotrol, Inc., with emissions estimated at 251 pounds per day or about 74% of the 340 pounds per day of ethylene oxide emitted from all surveyed sources in the inventory area. Ethylene oxide emissions from all surveyed hospitals total about 70 pounds per day. Table C-1 shows the ethylene oxide emission data for all of the sources modeled.

FIGURE C-1

MAP OF ETHYLENE OXIDE MODELING AREA



The Industrial Source Complex Short Term (ISCST) air quality model was used to predict annual ethylene oxide concentrations for a gridded array of receptors spaced one kilometer apart. For the exposure estimates, the population contained in each one kilometer-square grid cell is assumed to be exposed to the ethylene oxide concentration estimated for the receptor node located at the center of the cell. The receptor area contains 71 grid cells in the east-west direction and 45 grid cells in the north-south direction.

Several subgrids of the 71 by 45 kilometer modeling region were used depending on the emission source location to save on computer costs. Groups of sources were selected so they would be centered in a 50 by 34 kilometer grid. Micro-Biotrol, Inc. was centered in a 60 by 40 kilometer grid. The central position of the modeling region is common to all grids. Receptor indexing for all subgrids was adjusted to the 71 by 45 kilometer grid. Concentrations from each set of sources modeled were then summed at each receptor to estimate cumulative concentrations at each receptor in the exposure area.

III. RESULTS

The estimated population-weighted 1985 annual mean ethylene oxide concentration from all sources in the inventory area is 50 parts per trillion (ppt). The most exposed five percent of the exposure area population of 6,862,631 (343,132 people) is estimated to be exposed to 160 ppt or more, annually. (Note that people in the exposure area are also exposed to ethylene oxide emissions from sources outside the inventory area.)

Micro-Biotrol, Inc. accounts for about 74% of the ethylene oxide emissions, and the residential exposure to ethylene oxide from this facility is about 81% of the total exposure. The percentage for exposure is higher because most of the ethylene oxide from Micro-Biotrol, Inc. is emitted during

TABLE C-1

ETHYLENE OXIDE EMISSION DATA

Rank	Facility	ETO (pounds/day)	Stack Height (feet)	Distance to Nearest Receptor (meters)
INDUSTRIES				
1.	Micro-Biotrol, Inc.	251	45	316
2.	MG Industries	16	40	447
3.	Liquid Carbonic Corp.	6.4	3	361
HOSPITALS				
4.	St. John's Hospital	6.05	180	640
5.	UCLA Medical Center	5.78	0-112	300
6.	USC Medical Center	5.76	25-170	361
7.	VA Med. Center, Brentwood	5.36	120	566
8.	Huntington Memorial Hosp.	4.80	0	424
9.	Brotman Medical Center	4.71	81	400
10.	Hosp. of the Good Samaritan	2.78	122	412
11.	Daniel Freeman Mem. Hosp.	2.09	55	224
12.	Cedars-Sinai Med. Center	1.97	13	424
13.	Cigna Hospital of L.A.	1.85	14	640
14.	Beverly Hospital	1.80	7	583
15.	St. Vincent Med. Center	1.69	21	424
16.	Garfield Medical Center	1.54	54	447
17.	Orthopedic Hospital	1.54	0	539
18.	Rancho Los Amigos Hosp.	1.32	27	200
19.	Midway Hosp. Med. Center	1.30	27	447
20.	Alhambra Comm. Hospital	1.20	54	640
21.	Memorial Hosp. Glendale	1.12	122	500
22.	St. Francis Med. Center	1.12	30	510
23.	Kaiser Hosp - Bellflower	0.90	0	316
24.	Santa Monica Med. Center	0.90	162	224
25.	R.F. Kennedy Med. Center	0.70	14	283
26.	Downey Comm. Hospital	0.67	0	500
27.	Centinela Hospital	0.65	100	566
28.	Kaiser Hosp - Sunset	0.62	27	640
29.	Kaiser Hosp - West L.A.	0.62	27	400
30.	Children's Hosp. of L.A.	0.60	14	412
31.	Century City Hospital	0.58	14	500
32.	Hollywood Presbyterian	0.56	81	316
33.	White Memorial Hospital	0.56	68	510
34.	L.A. County-M.L. King	0.50	120	224
35.	Calif. Hosp. Med. Center	0.45	122	200

TABLE C-1 - continued

ETHYLENE OXIDE EMISSION DATA

Rank	Facility	ETO (pounds/day)	Stack Height (feet)	Distance to Nearest Receptor (meters)
36.	Westside Hospital	0.42	40	500
37.	Coast Plaza Med. Center	0.40	14	539
38.	L.A. Doctors Hospital	0.34	14	361
39.	Beverly Hills Med. Cen.	0.32	94	100
40.	Comm. Hosp. San Gabriel	0.32	0	316
41.	Maxicare Medical Center	0.30	14	361
42.	Rio Hondo Mem. Hospital	0.30	14	583
43.	Daniel Freeman Marina	0.28	11	100
44.	Queen of Angels Med. Cen.	0.28	300	100
45.	Barlow Hospital	0.27	22	141
46.	French Hospital of L.A.	0.27	27	141
47.	Temple Comm. Hospital	0.26	0	316
48.	Washington Medical Cen.	0.24	20	583
49.	Memorial Hosp. Hawthorne	0.22	27	100
50.	Monterey Park Hospital	0.22	27	1000
51.	Comm. Hosp. of Gardena	0.20	14	412
52.	Hollywood Comm. Hospital	0.18	0	510
53.	Charter Suburban Hosp.	0.09	14	583
54.	USC Compr. Health Center	0.09	30	566
55.	Santa Marta Hospital	0.05	40	224
56.	West Hollywood Hospital	0.04	14	224
57.	Inglewood Women's Hosp.	0.02	14	361
58.	East L.A. Doctors Hosp.	0.01	13	224
	Total	340		

the early morning or evening, when wind speeds are low and the air is relatively stable. Under such conditions, relatively high ground level concentrations are expected to occur.

The complete population exposure distribution attributed to emissions from all sources, and from Micro-Biotrol alone, is given in Table C-2. Figure C-2 shows the annual ethylene oxide concentration distribution resulting from emissions from all sources in the inventory area, as well as the 1985 population distribution for the exposure area. Figure C-3 shows the annual ethylene oxide concentration distribution from all hospitals in the inventory area, along with the same population distribution as in Figure C-2. Figure C-4 shows the annual ethylene oxide concentration distribution from Micro-Biotrol, Inc., along with the same population distribution as in Figure C-2. Figures C-5 and C-6 represent exposure, the product of the annual concentration multiplied by the population for each one kilometer grid cell in the modeling region. Figure C-5 shows the annual ethylene oxide exposure distribution, from Micro-Biotrol, Inc., and from all hospitals in the inventory area; and Figure C-6 shows the annual ethylene oxide exposure from all sources in the inventory area. The vertical scales are the same for all three plots so that they can be visually compared. Figure C-7 shows the cumulative population exposure distribution for all residents in the exposure area, due to emissions from all sources in the smaller inventory area. Figure C-8 shows the percentage of residential exposure attributed to the three source categories.

TABLE C-2

POPULATION EXPOSURE DISTRIBUTION TO ETHYLENE OXIDE
IN THE SOUTH COAST AIR BASIN EXPOSURE AREA, 1985

Annual Exposure Range (ppt)	Population Exposed			
	Micro-Biotrol		All Sources	
	Incremental	Cumulative	Incremental	Cumulative
>0 - 10	1,402,411	6,185,840	1,599,030	6,862,631
10 - 20	1,245,825	4,783,429	935,913	5,263,601
20 - 30	950,536	3,537,604	692,118	4,327,688
30 - 40	691,861	2,587,008	753,437	3,635,570
40 - 50	490,776	1,895,207	609,460	2,882,133
50 - 100	841,033	1,404,431	1,522,038	2,272,673
100 - 150	248,160	563,398	377,107	750,635
150 - 200	100,365	315,238	123,560	373,528
200 - 250	73,575	214,873	84,136	249,968
250 - 300	52,253	141,298	51,036	165,832
300 - 350	14,305	89,045	35,410	114,796
350 - 400	41,807	74,740	42,120	79.386
400 - 450	1,962	32,933	551	37,266
450 - 500	10,874	30,971	10,874	36,715
500 - 550	4,572	20,097	6,247	25,841
550 - 600	0	15,525	27	19,594
600 - 650	2,395	15,525	2,395	19,567
650 - 700	2,239	13,130	4,843	17,172
700 - 750	1,032	10,891	1,032	12,329
750 - 800	2,346	9,859	1,786	11,297
800 - 850	27	7,513	1,998	9,511
850 - 900	0	7,486	27	7,513
900 - 950	396	7,486	396	7,486
1400 - 1450	1,065	7,090	1,065	7,090
1700 - 1750	6,025	6,025	6,025	6,025
	6,185,840		6,862,631	

Antelope Valley Hospital Medical Center
avhmc
1600 WEST AVENUE J, LANCASTER, CALIFORNIA 93534 (805) 949-5065

RECEIVED
NOV 8 1985
Stationary Source Division
Air Resources Board

November 4, 1985

Air Resources Board
1102 "Q" Street
P. O. Box 2815
Sacramento, CA 95812

In reply to your communication of October 16, 1985:

At this time, our facility has no information on the health effects of Ethylene Oxide to submit for your study.

I would be happy to receive information inquiries for other candidate substances and will route them to the appropriate individual in our facility qualified to respond.

Yours truly,

Bonnie J. Aitken

Bonnie J. Aitken
Director, Materiel Management

cc: Chuck Herrera, Safety Committee
John Hamilton, Assistant Administrator

BECKMAN

BECKMAN INSTRUMENTS, INC.
SPINCO DIVISION
1050 Page Mill Road, Box 10200, Palo Alto, California 94304 • Telephone (415) 857-1150

November 4, 1985

Mr. William V. Loscutoff
Chief Toxic Pollutants Branch
RE: Ethylene Oxide
California Air Resources Board
P.O. Box 2815
Sacramento, CA. 95812

Dear Mr. Loscutoff:

In reference to your memo of October 28, 1985 refering on the health effects of Ethylene Oxide as part of toxic air contaminant program, I have checked all our chemical departments.

We do not use any Ethylene Oxide in any of our processes and operations.

Sincerely,

John Berger
Manager of Regulatory Compliance

JB/db

Louisiana Department of Environmental Quality

PATRICIA L. NORTON
SECRETARY

OFFICE OF AIR QUALITY AND NUCLEAR ENERGY

GREG J. GASPERECZ
ASSISTANT SECRETARY

RECEIVED
NOV 18 1985
Stationary Source
Division
Air Resources Board

November 8, 1985

Mr. Peter D. Venturini
Chief, Stationary Source Division
Air Resources Board
State of California
1102 Q Street
Post Office Box 2815
Sacramento, California 95812

RE: Ethylene Oxide

Dear Mr. Venturini:

Thanks for your letter of October 28, 1985. We do not have any information, concerning ethylene oxide, to submit at this time. However, we do wish to continue receiving information inquiries for other candidate substances regarding toxic air contaminants.

Yours very truly,

GREG J. GASPERECZ
Assistant Secretary

GJG:EC:jcp

AIR QUALITY DIVISION • P.O. BOX 44096 • BATON ROUGE, LOUISIANA 70804 • PHONE (504) 342-1206

OCAW

Oil, Chemical & Atomic Workers
International Union, AFL-CIO

Joseph Misbrener, President
Michael Ricigliano, Secretary-Treasurer
L. Calvin Moore, Vice President
Robert E. Wages, Vice President

International Offices:
255 Union Blvd., Lakewood, CO 80228
303/987-2229

Mail: P.O. Box 2812, Denver, CO 80201

RECEIVED

NOV 18 1985

Stationary Source
Division
Air Resources Board

November 13, 1985

Peter D. Venturini
Chief Stationary Source Division
Air Resource Board
P. O. Box 2815
Sacremento, CA 95812

Re: Request for information regarding
Ethylene Oxide

Dear Mr. Venturini:

Reference is made to your request for information regarding ethylene oxide dated October 28, 1985.

Please be advised that the Oil, Chemical and Atomic Workers International Union does not believe it has any relevant information that is not available to you in the course of your reference search. Should we come across any information that might be of relevance, I will immediately forward same to Mr. Lascutoff.

Thank you for the invitation to participate. Please do not hesitate to contact me if you have any questions or if we can be of further assistance in any other Health and Safety matter.

Yours truly,

Dan C. Edwards

Dan C. Edwards
Director
Health and Safety Department

DCE:mr
cc: R. Wages, Vice President
J. Foley, Director District #1

KERN VALLEY HOSPITAL DISTRICT

Wm. W. Kissack, Pres.
Chuck Wild, Vice Pres.
Timothy P. Anderson, Sec.
Fred Dodds, Treas.
Robert Wolney, M.D., Asst. Sec.

6412 Laurel Ave.
Rt. 1, Box 152
Mt. Mesa
Lake Isabella, CA 93240-9729

D. E. Naworski
Chief Executive Officer

(619) 379-2681

November 4, 1985

William V. Loscutoff, Chief
Toxic Pollutants Branch
Re: Ethylene Oxide
California Air Resources Board
P.O. Box 2815
Sacramento, Ca 95812

Dear Mr. Loscutoff:

Our hospital is not now or are we planning on using Ethylene Oxide as a for of sterilization at any time in the forseeable future. If you have any questions please feel free to contact me at the above listed telephone number.

Cordially,

Robert V. Pierce Jr. RN
O.R. Supervisor

HEMET VALLEY HOSPITAL DISTRICT

THOMAS J. BRODERICK, M.B.A.
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November 6, 1985

William V. Loscutoff, Chief
Toxic Pollutants Branch
California Air Resources Board
1102 Q Street
P.O. Box 2815
Sacramento, CA 95812

Dear Sir:

In response to your request for information regarding Ethylene Oxide, October 28, 1985 I am forwarding to you for your review and consideration a reference copy that was not listed on your bibliography. The Council on Scientific Affairs', Advisory Panel on Reproductive Hazards in the Workplace of the American Medical Association published their report Effects of Toxic Chemicals on the Reproductive System, June 1985. Ethylene Oxide is only one of a total 120 chemicals considered for review based on an estimation of their imminent hazard, i.e., widespread use and/or inherent toxicity.

Thank you for requesting relevant information concerning ethylene oxide.

Yours truly,

Sharon LaHaise

Sharon LaHaise, Ph.D., R.N., I.C.P.
Infection Surveillance Officer

SLH:jl

encl (3)

STATE OF RHODE ISLAND AND PROVIDENCE PLANTATIONS

DEPARTMENT OF ENVIRONMENTAL MANAGEMENT
75 Davis Street
Providence, R. I. 02908

7 November 1985

Mr. William V. Loscutoff, Chief
Toxic Pollutants Branch
California Air Resources Board
P.O. Box 2815
Sacramento, CA 95812

Dear Mr. Loscutoff:

Your letter requesting information about ethylene oxide has been forwarded to my desk. Although I do not have additional information about this substance, I would appreciate receiving future information inquiries.

Thank you.

Very truly yours,

Barbara Morin

Barbara H. Morin
Senior Engineer
Division of Air and Hazardous
Materials

BHM:jg

New York State Department of Environmental Conservation
50 Wolf Road, Albany, New York 12233-0001

1885 NYS Forest Preserve Centennial 100

Henry G. Williams
Commissioner

November 7, 1985

Mr. William V. Loscutoff, Chief
Toxic Pollutants Branch
California Air Resources Board
P.O. Box 2815
Sacramento, CA 95812

RE: Ethylene Oxide

Dear Mr. Loscutoff:

According to our guidelines of Air Guide-1, in 1983 we reclassified ethylene oxide from a compound exhibiting a moderate degree of toxicity to a high toxic air contaminant. This was based on the modified TLV value for ethylene oxide by the ACGIH in 1982.

Presently, the inclusion of ethylene oxide as a high toxic air contaminant prevails as a guideline in the State of New York.

Enclosed is the information supporting our decision on this matter.

If you have any comments, we would like to hear from you. I can be reached at (518) 457-7454.

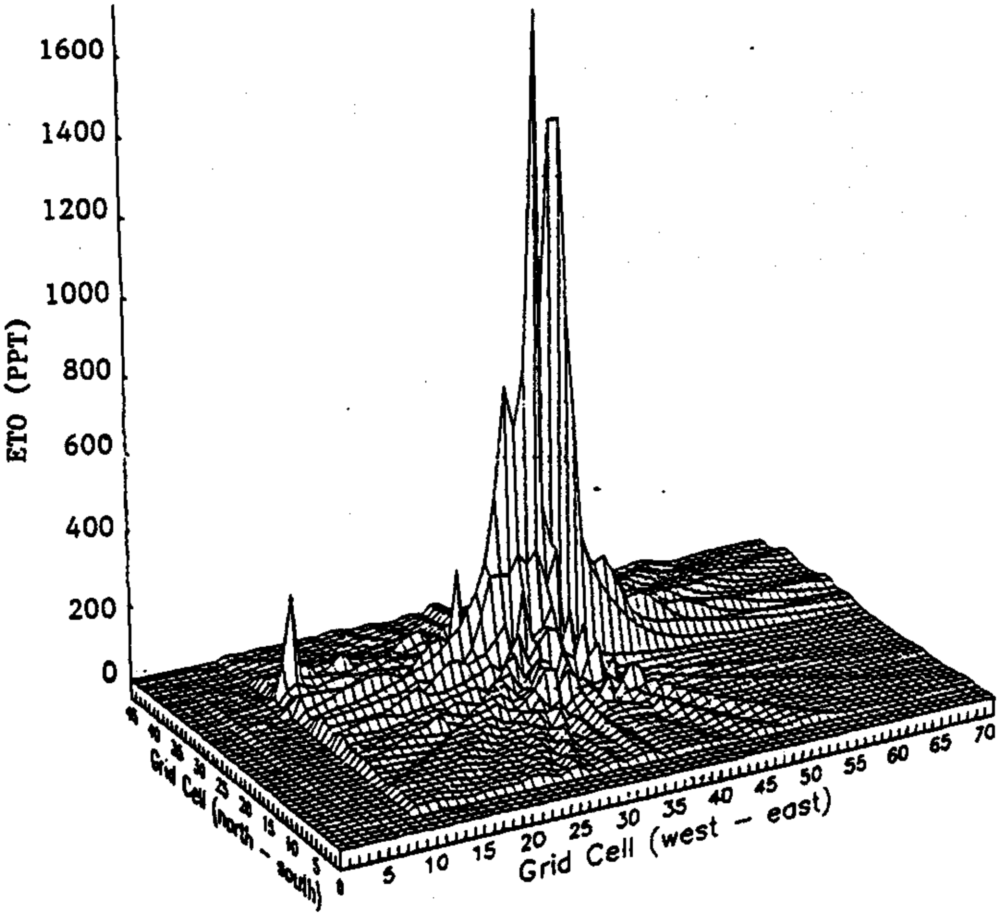
Sincerely,

Carlos L. Montes
Research Scientist
Bureau of Air Toxics

Enclosure
CLM/rg

FIGURE C-2

ETHYLENE OXIDE CONCENTRATIONS IN THE EXPOSURE AREA FROM ALL SOURCES IN THE INVENTORY AREA



1985 POPULATION DISTRIBUTION IN EXPOSURE AREA
(thousands people/cell)

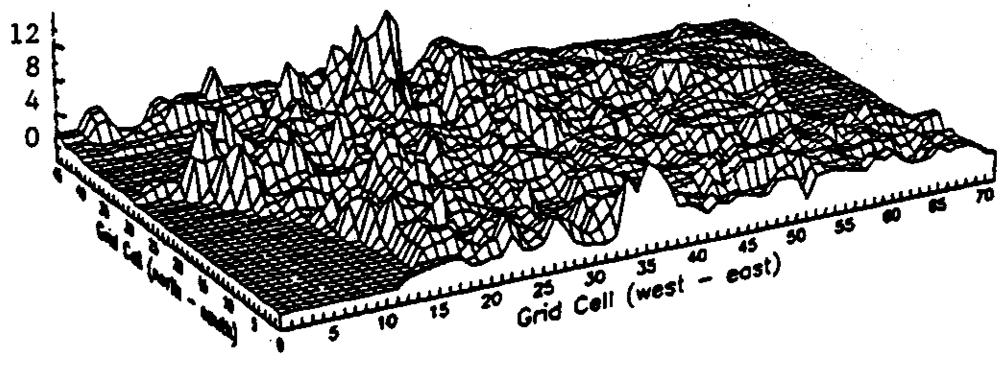
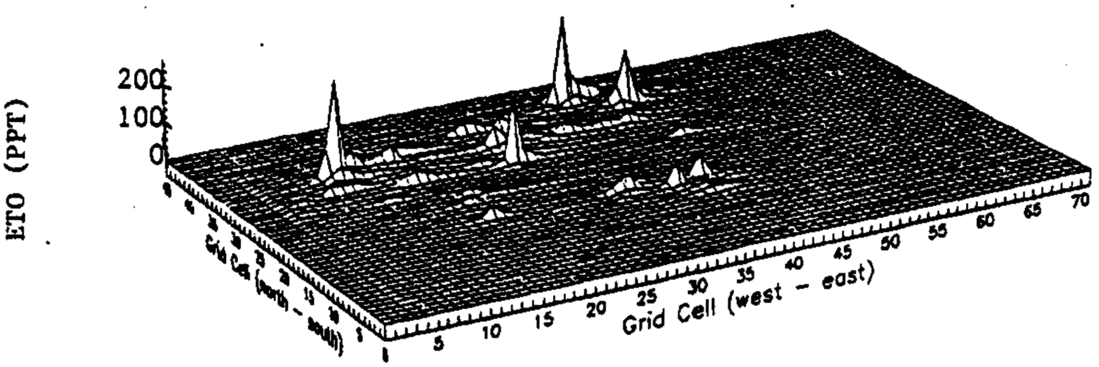


Figure C-3

ANNUAL ETHYLENE OXIDE CONCENTRATIONS FROM ALL HOSPITALS IN THE INVENTORY AREA



1985 POPULATION DISTRIBUTION IN THE EXPOSURE AREA (thousands people/cell)

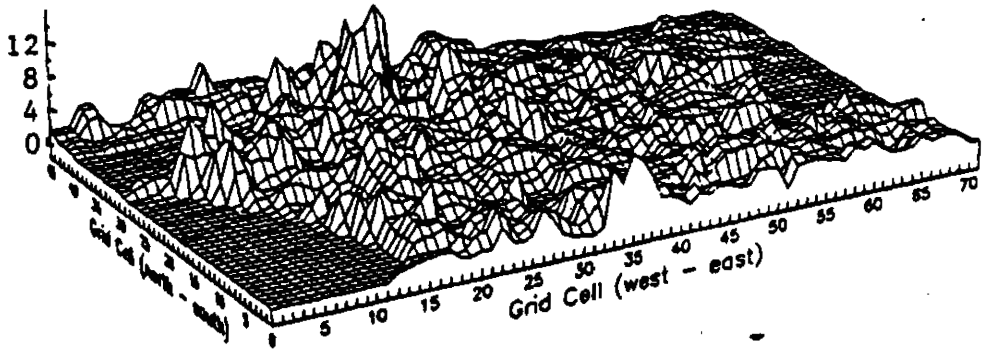
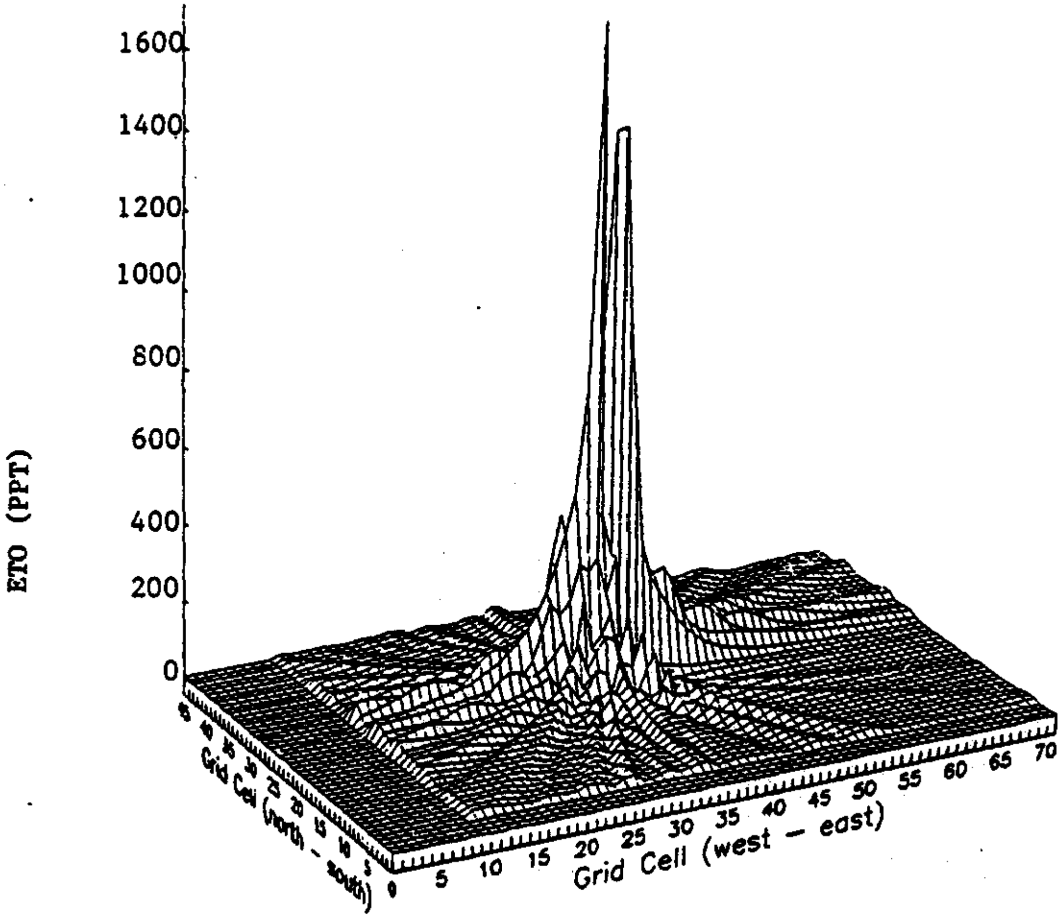


Figure C-4

ANNUAL AVERAGE ETHYLENE OXIDE CONCENTRATIONS FROM MICRO-BIOTROL



1985 POPULATION DISTRIBUTION IN THE EXPOSURE AREA
(thousands people/cell)

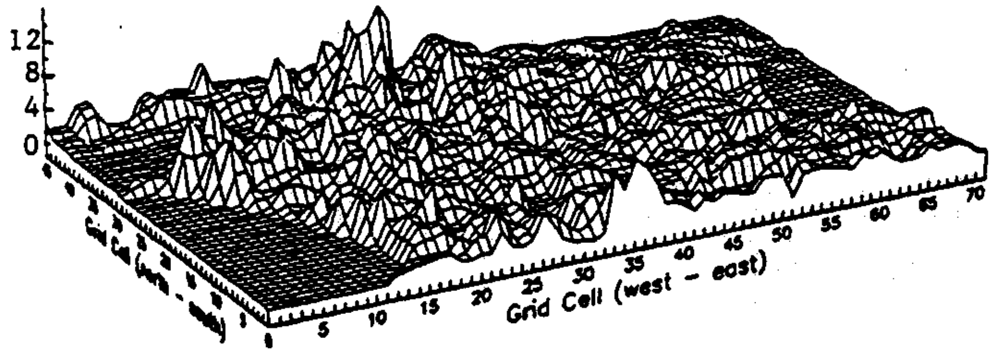
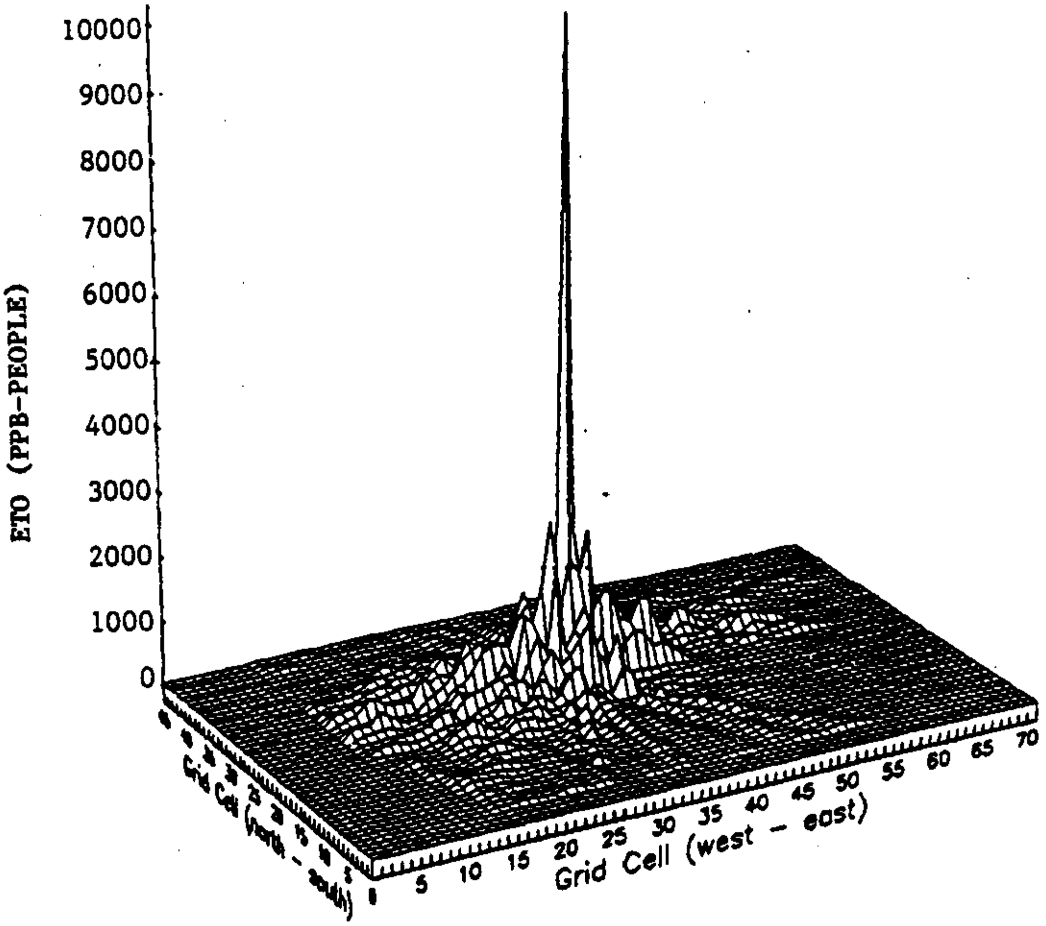


Figure C-5

ANNUAL ETHYLENE OXIDE EXPOSURE DUE TO EMISSIONS FROM MICRO-BIOTROL



ANNUAL ETHYLENE OXIDE EXPOSURE DUE TO EMISSIONS FROM ALL HOSPITALS IN THE INVENTORY AREA

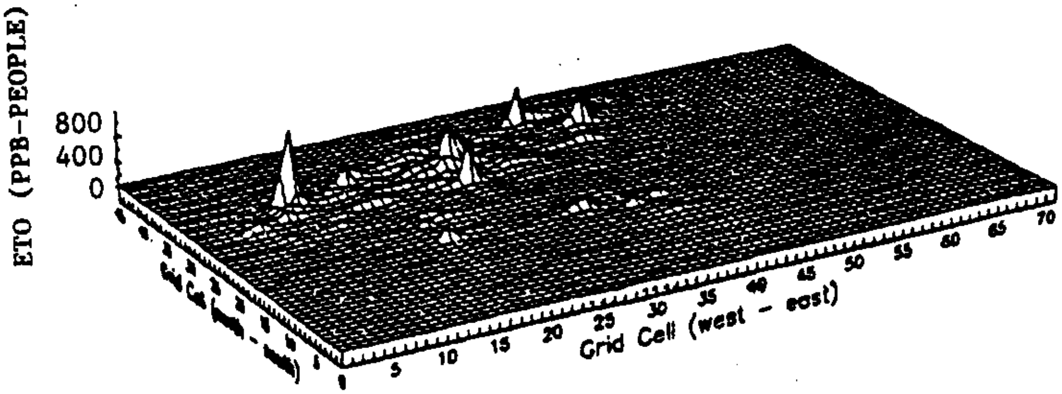


Figure C-6

ANNUAL ETHYLENE OXIDE EXPOSURE IN THE INVENTORY AREA DUE TO EMISSIONS FROM ALL SOURCES

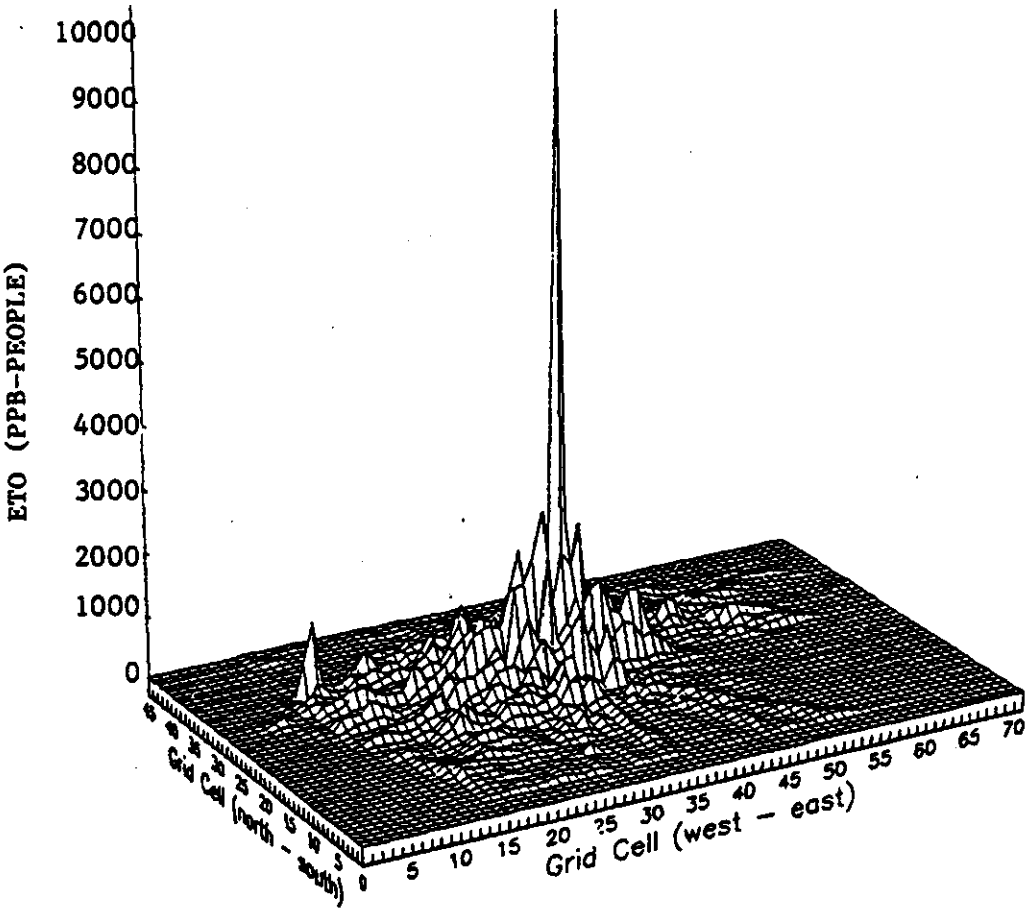


Figure C-7

RESIDENTIAL EXPOSURE TO ETHYLENE OXIDE
SOUTH COAST AIR BASIN EXPOSURE AREA - 1985

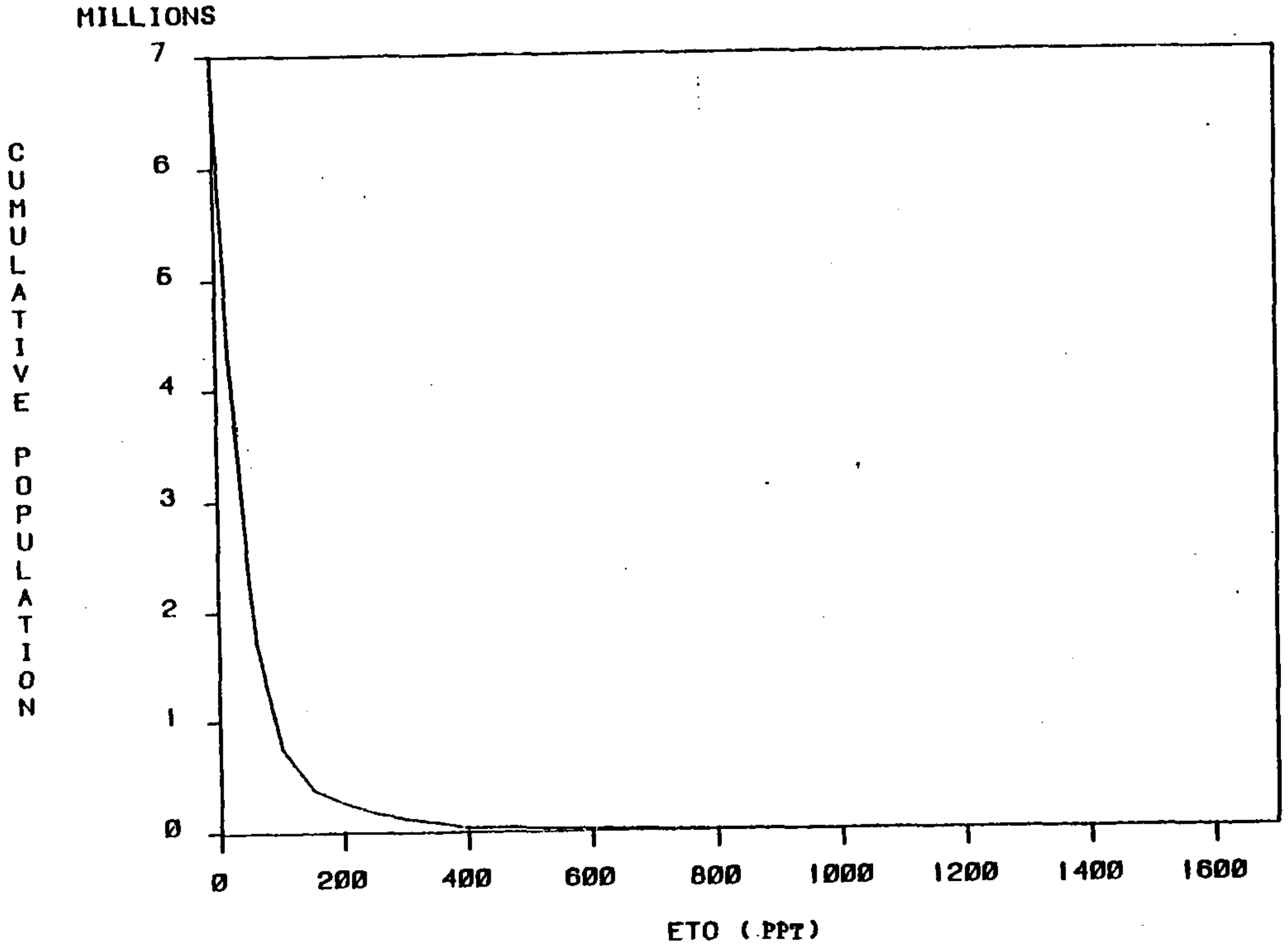
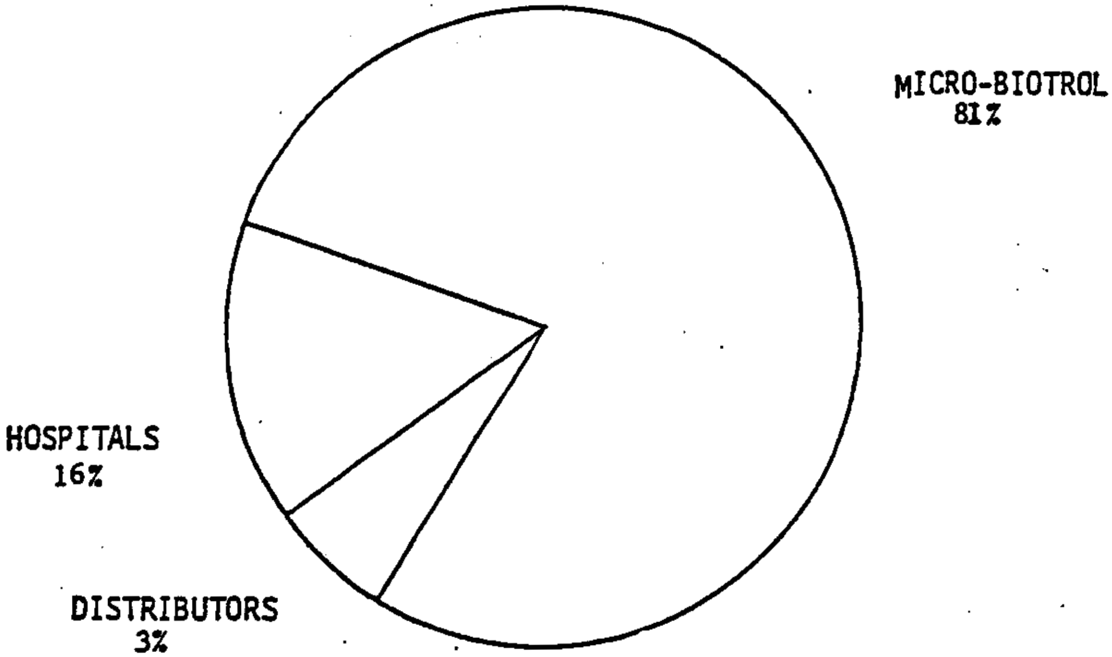


Figure C-8

RESIDENTIAL EXPOSURE TO ETHYLENE OXIDE BY SOURCE CATEGORY



APPENDIX D

POINT SOURCE MODELING METHODS AND RESULTS

POINT SOURCES MODELING METHODS AND RESULTS

In order to determine the extent of ethylene oxide exposure to people residing near point emission sources of ethylene oxide, the ARB modeled emissions from several industrial facilities in California. In addition, a comparison was made to EPA's analysis of exposures to ethylene oxide from two point sources in Santa Clara County (EPA, 1986). The latter analysis was conducted because of concern that exposure to airborne ethylene oxide might be responsible for high individual risks for maximally exposed individuals. The discussion below is divided into pesticidal sources and non-pesticidal sources for the convenience of the reader; however, ARB used the same modeling method for both types of sources.

I. NON-PESTICIDAL SOURCES

The Industrial Source Complex-Short Term (ISCST) air quality model was used to predict ethylene oxide concentrations for each of the ethylene oxide distribution facilities in the inventory area. The model includes a gridded array of receptors spaced one kilometer apart. For the exposure estimates, the population contained in each one kilometer-square grid cell is assumed to be exposed to the ethylene oxide concentration estimated for the receptor node at the center of the cell.

The ISCST model requires as input the emission and stack parameters, and one complete year (8760 hours) of meteorological data in order to calculate exposure estimates. For both facilities, meteorological data used in the ISCST model was measured at the Los Angeles International Airport (LAX) during

1978. This year was selected because it was the most recent year for which hourly records were available and it represents a poor year in terms of pollutant dispersion throughout the South Coast Air Basin.

Based upon information provided by the companies (see Section on emission sources in the main report for discussion), the following data was used as input to the ISCST model:

1) Liquid Carbonic Corp. - 0.8 pounds per hour emitted between 6:30 A.M. and 3:00 P.M. daily, from a three foot elevation.
2) MG Industries - 3.16 pounds per hour emitted between 7:00 A.M. and noon daily, from a 40-foot elevation.

Figures D-1 through D-4 show annual ethylene oxide concentrations and exposures that result from emissions from the Liquid Carbonic and MG Industries facilities.

II. PESTICIDAL SOURCES

Subsections 1 and 2 below provide results of modeling studies conducted by ARB for two industrial sterilizer/fumigation facilities in California. Subsection 3 provides results of modeling studies conducted by Versar Inc. (for EPA) for one hospital and one industrial sterilizing facility in the Bay Area Air Basin. Subsection 4 compares the results of modeling of point sources conducted by ARB and those reported by EPA. Despite differences in type of model, meteorology, stack height, and other factors, the results are generally consistent with each other.

1) Micro-Biotrol, Inc.

ARB modeled emissions from the Micro-Biotrol, Inc. contract sterilizing facility in Vernon (near Los Angeles). This was conducted as part of the study described in Appendix C, South Coast Area Modeling Methods and Results. Table 2 in Appendix C shows the exposure distribution for the modeling region

Figure D-1

ANNUAL ETHYLENE OXIDE CONCENTRATIONS FROM
LIQUID CARBONICS

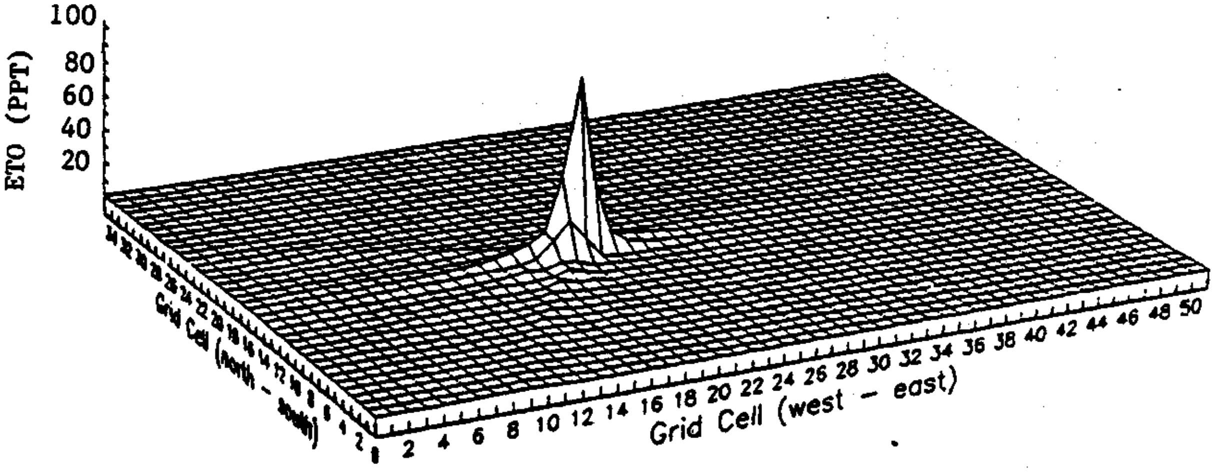


Figure D-2

ANNUAL ETHYLENE OXIDE CONCENTRATIONS FROM MG INDUSTRIES

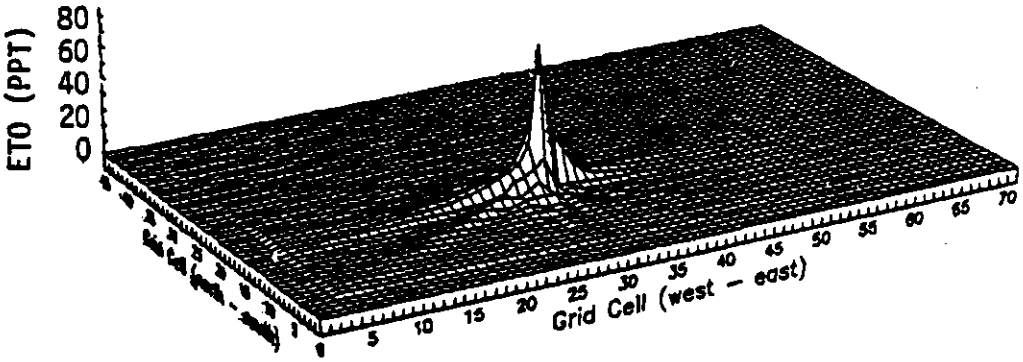


Figure D-3

ANNUAL ETHYLENE OXIDE EXPOSURE FROM LIQUID CARBONICS

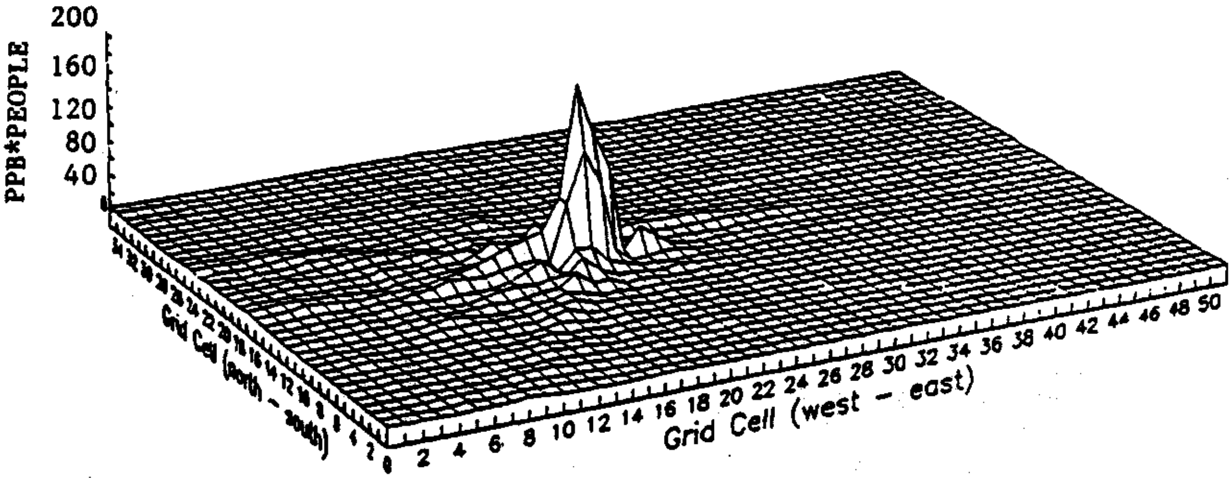
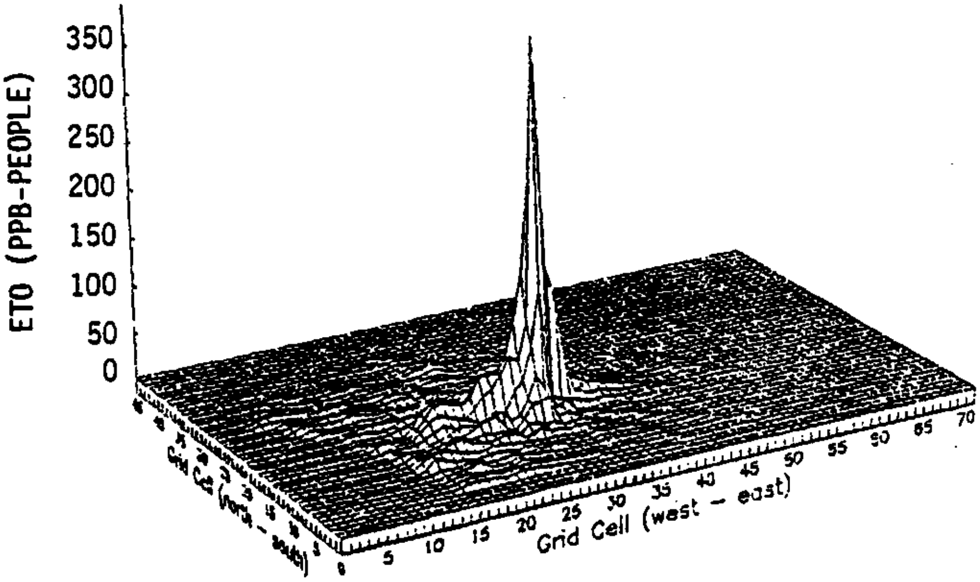


Figure D-4

ANNUAL ETHYLENE OXIDE EXPOSURE FROM MG INDUSTRIES



and the ethylene oxide exposure distribution due only to emissions from Micro-Biotrol, Inc. The modeling study provided estimates of annual concentrations of up to 1700 ppt near Micro-Biotrol.

From information provided by the company to ARB in May, 1986, it was calculated that 45.9 tons of ethylene oxide were used in 1985 (about 251 pounds per day). (For 1984, the South Coast Air Quality Management District (SCAQMD) estimated emissions of 71 tons of ethylene oxide.) The company estimates that 90% of the sterilant charge used is actively exhausted with the sterilizer door closed, near the end of the sterilization cycle. 40% of the emissions occur between 4 A.M. and 6 A.M, 40% between 8 P.M. and 11 P.M., and 20% between 8 A.M. and 5 P.M. The ethylene oxide is exhausted to the 45 foot-high roof at 140°F. For modeling purposes, 90.48 pounds were assumed to be emitted at 5 A.M. and again at 9:30 P.M., every day; and 22.62 pounds were assumed to be emitted each day at both 11 A.M. and 2 P.M. These emission figures represent about 90% of ethylene oxide reported used by the company. The remainder was not included for modeling purposes, although it was included for inventory purposes.

As shown in Table D-1, the population-weighted annual average ethylene oxide concentration in the exposure area due only to ethylene oxide emissions from Micro-Biotrol, Inc. was estimated to be about 40 ppt. The highest annual concentration estimated for any of the one square kilometer receptor grids was 1700 ppt, located about one kilometer west of the emission source. However, since the receptors are spaced at one kilometer increments throughout the modeling region, they provide an estimate of regional-scale exposures to ethylene oxide rather than an estimate of the maximum ground level concentrations near specific facilities. To get a more accurate estimate of the maximum ground level concentration near the Micro-Biotrol, Inc. facility,

TABLE D-1

POPULATION-WEIGHTED ANNUAL AVERAGE ETHYLENE OXIDE CONCENTRATIONS*

Source	Mean (ppt)
Micro-Biotrol, Inc.	40
All Hospitals	8
Liquid Carbonic Corp.	1
MG Industries	1
All Sources	50

---

* The total population of the exposure area in 1985 was 6,862,631. All concentration figures are weighted for this total population. The most exposed five percent of the population would be exposed to concentrations of 160 ppt or greater.

ARB used a 50 by 50 meter receptor grid for a three by three kilometer area around the emission source. The highest annual concentration estimated for these 50 meter receptors is 10,000 ppt, located about 250 meters east of the source. This value would approximate the highest concentration that could be breathed by maximally exposed individuals. Appendix C describes the modeling procedure further.

2) Schilling Spice Co.

In August, 1983, ARB staff conducted a source test (ARB, 1983) at the McCormick and Co., Inc. (Schilling) facility in Salinas which determined that approximately 20 percent of the ethylene oxide charged to the sterilization chamber was directly emitted to the air through two small stacks. Another 35-40 percent was determined to be going into the wastewater. The remaining 40-45 percent of the ethylene oxide was presumed to be emitted from the aeration chamber, after the products were removed from the sterilization chamber. This latter percentage (40-45 percent) was therefore combined with the 20 percent directly emitted to the air, as total emissions modeled.

Because some ethylene oxide remains with products and associated materials and because some ethylene oxide is emitted during product transfer between chambers, the 40-45 percent value may overstate the emissions from the aeration chamber. However, ARB staff believes that a significant proportion of the 35-40 percent accounted for in the wastewater is in fact emitted to the air near the facility, due to ethylene oxide's appreciable chemical stability and volatility when dissolved in water (see discussion on properties in main report). 85% of the ethylene oxide used can be released at the drain opening (HIMA, 1980). However, for this modeling study, ethylene oxide accounted for in the wastewater was excluded.

ARB performed the modeling analysis utilizing the ISCST model. This model requires as input the emission and stack parameters, and one complete year (8760 hours) of meteorological data in order to calculate impacts for worst-case combinations of emissions and meteorology. For this analysis, meteorological data from Salinas Airport for 1961 were used.

Emission and stack parameters for the facility are presented in the following table. The maximum annual ethylene oxide impact based on a five-day work week is 21,400 parts per trillion (ppt) above ambient level, and is located approximately 100 meters due west of the facility.

	Stack #1	Secondary Vent	Aeration Room Vent
Stack height (m)	5.2	3.7	8.5
Stack temperature (°K.)	302	303	293
Flow rate (m^3/sec)	0.052	0.071	1.417
Stack diameter (m)	0.15	0.10	0.42
Stack gas velocity (m/sec)	2.94	7.47	10.3

Stack #1 and secondary vent emissions occurred for one hour periods, starting at 11 A.M., 4 P.M., 9 P.M., and 2 A.M. The vent emission rate was 1.26 g/sec. for stack #1, and 0.065 g/sec. for the secondary vent. The aeration room was vented for four hour periods, starting at 11 A.M., 4 P.M., 10 P.M., and 3 A.M.; with emission rates of 0.6 g/sec.

For the purpose of establishing the numbers of people living at various distances from the plant, 1980 census tract data were utilized. These data showed that about 4,000 people live within a one mile radius of the plant. Annual average concentration isopleths were generated by modeling that led to the following conclusions.

The estimated maximum annual ethylene oxide concentration was 21,400 parts per trillion (ppt) or 38.5 ug/m^3. Using 1980 census tract data, these emissions resulted in an estimated 240 people being exposed to annual average concentrations between 310 and 3,100 ppt, and an estimated 24,000 people being exposed to annual average concentrations between 31 ppt and 310 ppt.

3) Santa Clara Valley Project

In June, 1985, Versar Inc. submitted a "Follow-up Air Quality Analysis in Support of the Integrated Environmental Management Division's Santa Clara Project" to EPA (Versar, 1985). As part of this project study of Santa Clara County, two ethylene oxide emission sources were modeled. Good Samaritan Hospital, a 403 bed hospital in San Jose, was estimated in the report to emit 750 kg/year of ethylene oxide. The report states, "the predicted annual concentrations for the most exposed individual is conservatively estimated to be roughly 1.9 ug/m^3" (1,000 ppt). The report also provides a prediction for maximum ethylene oxide concentration from the hospital of about 2.2 ug/m^3 (1,200 ppt).

Good Samaritan Hospital uses 106 tanks of disinfecting gas per year. The tanks contain 130 pounds each with 12% ethylene oxide (ETO) by weight. Therefore, annual emissions are about 750 kg. (Soffer, 1986).

$$\left(\frac{\text{130 lb gas}}{\text{tank}}\right) \times \left(\frac{\text{.12 ETO}}{\text{gas}}\right) \times \left(\frac{\text{106 tanks}}{\text{year}}\right) \times \left(\frac{\text{1 kg}}{\text{2.2 lb}}\right) = \frac{\text{752 kg}}{\text{year}}$$

All gas in the tanks was assumed to be emitted at the hospital.

The Versar report (Versar, 1985) also provides an emission estimate of 1,540 kg/year for an industrial source of ethylene oxide, Barnes-Hind Pharmaceuticals, Inc., in Sunnyvale, CA. With modeling, the maximum predicted annual concentration of ethylene oxide was 4.4 ug/m^3, or 2,450 ppt.

The emission estimate for Barnes-Hind Pharmaceuticals, Inc. used by Versar Inc. (1,540 kg/year) differs from that obtained from the Bay Area Air Quality Management District (BAAQMD, 1984). The BAAQMD estimated six tons per year (5,460 kg/year) from that facility, or about 3.5 times as much. Modeling with the higher BAAQMD emission estimates might then predict a maximum annual concentration of 15.6 ug/m^3 (8,700 ppt) ethylene oxide.

For both facilities, Versar Inc. used the LONGZ model (Versar, 1985), a computer program designed to calculate long-term ground-level pollutant concentrations utilizing a multiple number of source types and receptors. It uses the steady-state univariate Gaussian plume formulation.

4) Modeling Discussion

The maximum concentration for Micro-Biotrol, Inc. can be compared to maximum concentrations from other ethylene oxide (ETO) modeling studies performed for various sources. For ease of comparison, the results are shown in the following table:

Ethylene oxide Emission Source	Maximum Annual Concentration (ppt)	ETO Emission Rate (pounds/day)	Stack Height (meter)	Emission/ Concentration Ratio*
Micro-Biotrol	10,000	251	14	25
Schilling	21,400	119	5	5.6
Barnes-Hind	2,400	9	5	3.8

* The "emission/concentration ratio" is obtained by dividing the ethylene oxide emission rate by the maximum annual concentration.

Both the modeling study of Schilling conducted by ARB and the modeling study of Barnes-Hind conducted by Versar Inc. used receptor locations designed to predict maximum concentrations. Comparing the results, Micro-Biotrol has the highest emission/concentration ratio. Micro-Biotrol also has the highest stack at 14 meters. The other sources have stacks of about 5 meters. The higher stack at Micro-Biotrol tends to produce lower maximum concentrations at ground level due to greater dispersion of emissions, thereby increasing the emission/concentration ratio. Given the fact that the meteorology is different for all three studies, the results appear to be consistent, in terms of emission/concentration ratios for the maximum ground level concentrations.

REFERENCES - APPENDIX D

ARB, 1983. Performance Evaluation Test Reports C-83-004 and C-83-049, Stationary Source Division.

BAAQMD, 1984. 1984 Toxic Use Survey: Bay Area Air Quality Management District. Prepared by Steve Hill, Senior Air Quality Engineer, BAAQMD, December, 1985.

EPA, 1986. Santa Clara Valley Integrated Environmental Management Project, Revised Stage One Report. Office of Policy, Planning, and Evaluation, EPA, May 30, 1986.

HIMA, 1980. "Safe Use of Ethylene Oxide," Report #80.4, Health Industry Manufacturers Association.

Soffer, 1986. Telephone communication between Eileen Soffer, EPA Region IX, and Ralph Propper, ARB. Eileen Soffer obtained the data through a personal communication from David Sullivan of Good Samaritan Hospital.

Versar, 1985. "Follow-up Air Quality Analysis in Support of the Integrated Environmental Management Division's Santa Clara Project"; prepared for Forest Reinhard, Task Manager; Office of Policy, Planning and Evaluation; Integrated Environmental Management Division; Geographic Branch, EPA; by Versar Inc., June 12, 1985.

APPENDIX E

EXPOSURE TO ETHYLENE OXIDE THROUGH OTHER MEDIA

EXPOSURE TO ETHYLENE OXIDE THROUGH OTHER MEDIA -

Estimated Ethylene Oxide Inhalation and Ingestion Rates

SMOKERS

Binder and Lindner (1972) estimated that the ethylene oxide concentration of unfumigated tobacco smoke is 0.02 micrograms per milliliter. Standard smoking conditions include 35 ml. puffs, and one cigarette averages roughly ten puffs under these conditions (Higgins, 1983). A pack contains 20 cigarettes, so a one-pack-a-day smoker inhales:

$$\frac{0.02\ \text{ug}}{\text{ml}} \times \frac{35\ \text{ml}}{\text{puff}} \times \frac{10\ \text{puffs}}{\text{cigarette}} \times \frac{20\ \text{cigarettes}}{\text{day}} = \frac{140\ \text{ug}}{\text{day}}$$

AMBIENT AIR

An individual exposed to 50 ppt ethylene oxide (EO) concentration of ambient air (the average estimated for the South Coast exposure region described in Section I-A), who inhales the average 20 cubic meters per day, inhales:

$$\frac{50\ \text{parts EO}}{10^{12}\ \text{parts air}} \times \frac{44\ \text{g}}{22.4\ \text{l.EO}} \times \frac{1000\ \text{l.}}{\text{meter}^3} \times \frac{20\ \text{meter}^3}{\text{day}} \times \frac{10^6\ \text{ug}}{\text{g}} =$$

= about 0.02 microgram/day

INGESTION

The National Toxicology Program, in its Fourth Annual Report on Carcinogens (NTP, 1985), cited an FDA communication for the estimate that "potential daily intake of ethylene oxide per person in the United States is estimated to be 10 micrograms." According to the FDA reference (Modderman, 1986), this estimate was made for the purpose of providing an upper limit to possible daily intake rates from food.

Calculations were made for intake resulting from direct food additives only, because FDA believed that intake from indirect food additives (from food packaging) was a much smaller quantity. Intake from fumigated food and spices was not considered.

Direct food additives include the ethylene oxide polymer derivatives called polysorbates (used as emulsifiers), and the ethylene oxide polymer used in beer. In both cases, it was hypothesized that ethylene oxide might off-gas from the polymer. Analytical detection limits for ethylene oxide in food additives range from 0.5 ppm, up to 200 ppm for the least sensitive method approved by the U.S. Pharmacopoeia. It was assumed, for the purpose of establishing an upper limit, that all food additives derived from ethylene oxide contain 200 ppm ethylene oxide. It was further assumed that all of this would be in the food for ingestion.

The intake of direct additives from food was estimated to be four milligrams per day, which was multiplied by 200 ppm ethylene oxide to obtain 8 micrograms ethylene oxide intake per day. In addition, based upon beer intake and the level of ethylene oxide polymer use in beer (assuming maximum levels in both cases), FDA estimated 2 micrograms ethylene oxide intake per day from beer consumption. By combining the intake from food and from beer, FDA obtained a maximum intake level of 10 micrograms per day.

REFERENCES - APPENDIX E

Binder, H. and W. Lindner, 1972. "Determination of Ethylene Oxide in the Smoke of Treated and Untreated Cigarettes," Fachliche Mitt. Oesterr. Tabakregie, 13: 215-220.

Higgins, 1983. J. Assoc. Offic. Analytical Chem. Vol. 66, Sept., 1983.

Modderman, John, 1986. Telephone communication between John Modderman, U.S. Food and Drug Administration, and Ralph Propper, ARB, October 15, 1986.

APPENDIX F

EMISSIONS OF ETHYLENE OXIDE FROM DISTRIBUTION FACILITIES

EMISSIONS OF ETHYLENE OXIDE FROM DISTRIBUTION FACILITIES

Routine releases of ethylene oxide attributable to distributors occur at plants where the ethylene oxide is mixed and repackaged for sale to retailers. Ethylene oxide mixed with dichlorodifluoromethane or carbon dioxide is sold in pressurized cylinders. When the cylinders are returned to the filling plant, residual gas is evacuated and the cylinders are then cleaned if necessary and refilled.

The ARB is aware of five ethylene oxide cylinder filling facilities in California. Two facilities are located in the Bay Area Air Basin and three are in the South Coast Air Basin. Liquid Carbonic, Inc. has one in San Carlos and another in Los Angeles. Union Carbide's Linde Division has one in Torrance and one in South San Francisco. M.G. Industries has one facility in Los Angeles.

For most plants, the major source of emissions is from disposal of residual sterilant gas mixture in cylinders returned for refilling. The amount returned in used tanks varies according to the specific practices and equipment employed by the user. Practices for disposal of the residual gas vary within the industry. Fugitive emissions represent another source of emissions, which may range from below 1/2% to 2% (Zwiacher 1983).

For cylinders of pure ethylene oxide, residual amounts are generally small. Cylinders of pure ethylene oxide used by industrial sterilizers are generally pressurized by the users with nitrogen gas to force out the ethylene oxide. The plant manager of one industrial sterilizing company reports he returns 1/2% to 1% of the pure ethylene oxide he buys (Knight, 1986). Hospital sterilizers which operate on pure ethylene oxide operate at a vacuum and the gas is packaged in disposable containers appropriate for one load.

Variable amounts of gas remain in returned cylinders of ethylene oxide sterilant gas mixture. Some factors which influence the amount of gas remaining in the cylinder are: (1) the make and model of sterilizer used, (2) the size of the sterilizer chamber, (3) the size of the gas cylinder in relation to the size of the sterilizer, and (4) the operating parameters such as temperature, pressure and duration of the sterilizing cycle. In addition, the gas has a limited shelf life because of the formation of non-volatile residual due to a catalyzed polymerization reaction.

ARB obtained information on both the amount of gas used and the amount purchased, for some of the hospitals surveyed. This data was used to calculate the percentage of gas purchased which was returned unused, and subsequently disposed. Percentages calculated for individual hospitals ranged from 7% to 46%. On the average 23% of the ethylene oxide purchased by hospitals was returned, presumably because it was either physically unavailable or because it was outdated.

Three additional sources of information were obtained. Union Carbide's distribution plant in South San Francisco recycles the residual ethylene oxide. In their pricing structure, the company assumes 6% to 7% of the gas will be reclaimed from returned cylinders. The Union Carbide plant in Torrance has applied to the South Coast Air Quality Management District (SCAQMD) for permission to build a new scrubber. For their application, volumes obtained from their recovery/recycling system were measured, over a period of time. These measurements established that an average of 18% of the ethylene oxide mixture they produced and packaged in cylinders was returned to them in used cylinders, or recycled because it was outdated (Bolen, 1986). Liquid Carbonic Corp. also measured the average return rate for their operation and found it to be lower than Union Carbide. Based on the limited data from these four sources, the percentage of ethylene oxide mixture returned in cylinders ranges from 4% to 47%.

Because the Union Carbide 18% return rate is near the average estimate for hospitals, ARB staff used the 18% return rate for the distributor which did not provide specific data.

Specific control measures used to reduce emissions vary. Union Carbide employed a recycling system to reclaim residual ethylene oxide. The Union Carbide facility in Torrance exhausted unreclaimed ethylene oxide through a scrubber using a 0.5 N sulfuric acid solution that was assumed by SCAQMD to be 90% effective in converting ethylene oxide to glycol. In 1985, the two Liquid Carbonic plants bubbled the residual ethylene oxide gas through water at a neutral or near neutral pH. ARB staff estimates this method to be 37% effective in removing ethylene oxide from the gas stream (ARB, 1983). However, since hydrolysis is very slow at near neutral pH, most of the ethylene oxide that is dissolved will re-volatilize within the air basin. At the MG Industries plant, the gas that is evacuated from returned tanks is released from a 40 foot high exhaust vent (Edwards, 1986).

The total emissions were calculated as a percentage of sterilant gas mixture production. The reduction due to control measures being used is subtracted and an estimated amount of fugitive emissions is added. Following are two examples of the type of calculation used:

Emissions = PFR (1-C) + PFE

where

P = production of sterilant gas mix

F = fraction of ethylene oxide in the sterilant mix

R = residual fraction returned

C = % controlled at plant

E = fugitive emission factor (1/2 to 2%)

e.g.,

Company X, C = 0

PFR (1-C) = 200,000 lb/yr X .12 X .18 (1 - 0) = 4,320 lb/yr

PFE = 200,000 lb/yr X .12 X .02 = 480 lb/yr

4,800 lb/yr =

2.4 tons/yr

Company Y

PFR (1-C) = 600,000 lb/yr X .12 X .18 (1-0.37) = 8,165 lb/yr

PFE = 600,000 lb/yr X .12 X .02 = 1,440 lb/yr

9,605 lb/yr =

4.8 tons/yr

REFERENCES - APPENDIX F

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APPENDIX G

EMISSIONS OF ETHYLENE OXIDE FROM HOSPITALS

EMISSIONS OF ETHYLENE OXIDE FROM HOSPITALS

This appendix describes the method by which statewide ethylene oxide emissions from hospitals were estimated, based on data obtained in the 1986 ARB survey of hospitals in the Los Angeles area. It also includes a discussion of the suitability of applying exposure estimates generated for the South Coast study area to statewide populations.

SOURCES OF EMISSIONS

Sterilization/fumigation equipment varies in size and operating characteristics according to the application. Typically, the equipment is a pressurized chamber, with a vacuum pump to remove air or the sterilant/air mixture from the chambers before and after sterilization. There are three categories of chamber size.

Small counter top models with capacities less than 0.1 m^3 (less than 4 ft^3) are used mostly in small hospitals, health care and health diagnosis facilities. These chambers generally use pure ethylene oxide supplied in single-dose cartridges. In these small units, ethylene oxide is usually vented to the outside atmosphere through a vent line.

Intermediate-sized chambers with capacities ranging from 0.1 to 2.8 m^3 (4-100 ft^3) are used primarily at hospital central supply facilities. These chambers generally use a 12% ethylene oxide/88% dichlorodifluoromethane (Freon-12) mixture supplied in pressurized cylinders. Ethylene oxide is usually vented to the outside atmosphere or sometimes is routed to a sewer drain near the chamber.

Large chambers have capacities of greater than 2.8 m^3 (100 ft^3). These are mainly used by contract sterilizers for industrial sterilization of medical and other products, by medical supplies manufacturers, and by spice companies for fumigation of spices. The chambers are designed to use either pure ethylene oxide or an ethylene oxide mixture suppied in pressurized cylinders or large tanks. Ethylene oxide is typically evacuated from the chamber using a water-sealed vacuum pump. Figure III-3 in the main report shows a flow diagram of a large ethylene oxide sterilizer chamber.

Sterilization with ethylene oxide in hospitals follows a generalized procedure as follows. The equipment to be sterilized is placed in a chamber from which most of the air is evacuated. The chamber is than warmed and humidified prior to introduction of the gas. The exposure phase begins with introduction of the gas and lasts two to five hours depending on the temperature at which the load is being run. The next step is the purge, during which the gas is evacuated and filtered air is bled in and pumped out several times. In the last step, aeration, the product is held at an elevated temperature while air is circulated through the chamber. Aeration is frequently done in a separate chamber. The purpose of the aeration phase is to promote desorption of ethylene oxide from product and packaging. Most hospitals aerate each load for 5 to 12 hours.

EMISSIONS EXTRAPOLATION

Data from the South Coast Air Basin study area was extrapolated to the state to estimate statewide emissions of ethylene oxide from hospitals. A list of all acute care hospitals in the state was assembled from data provided by the Licensing and Certification Division of the California Department of Health Services, the Veterans Administration, and the U.S. Army, Navy and Air Force. Data gathered for the modeling study of cumulative impact in an area of the South Coast Air Basin, as specified in Appendix C, was used to calculate emissions per hospital for three ranges of hospital size, in pounds of ethylene oxide per day per hospital.

All the hospitals in the state were then classified into the three size ranges, and the number of hospitals in each class was then multiplied by the average calculated emissions per hospital for that class. The following table gives the size ranges used, the average emissions per hospital in the South Coast inventory area, and the number of hospitals statewide in each size range. Multiplying the estimated emissions per hospital by the number of hospitals and summing the products for the three categories gives the statewide emissions estimate as follows:

Size (Beds)	Emissions/Hospital (Pounds ETO/day)	Number of Hospitals	Emissions (Pounds ETO/day)
1-200	.27	337	90.99
201-499	.87	167	145.29
Over 500	3.93	28	110.04
			346.32

$$346.32 \text{ lb./day} \times \frac{1 \text{ ton}}{2000 \text{ lb}} \times \frac{365 \text{ day}}{\text{year}} = 63.20 \text{ ton/year}$$

The following discussion identifies and, where possible, quantifies the uncertainties involved in this estimate. Because extrapolation involves predicting the behavior of a larger population based on that of a sample, several factors affect the resulting accuracy. For instance, if the sample is representative of the population and is a substantial proportion of the population and the extrapolation is based on a characteristic that correlates well with the variable being predicted, the accuracy of the extrapolation will be enhanced.

In this case, while there was a general upward trend in ethylene oxide use per bed with increasing hospital size, it was clear that several other variables affected the amount of ethylene oxide used by individual hospitals.

Ethylene oxide sterilization is utilized for heat-sensitive instruments that are used principally for surgical procedures and for respiratory therapy. Therefore, the fraction of beds occupied by patients requiring these services is an important variable. Other variables include the size, type, age and number of sterilizers in use; sterilizer operating variables such as temperature, pressure and duration of cycles and the extent to which disposable instruments are used. Because of these variables, the correlation between the number of beds and ethylene oxide use is low, and the corresponding uncertainties can not be quantified.

In the study area it was noted that as hospital size increased, the per-bed use of ethylene oxide also increased. This may be due to the following possibilities: 1) the small hospitals use more disposable instruments, 2) small hospitals contract more for off-site ethylene oxide sterilization, and 3) more complicated cases are treated at the larger hospitals.

Because the Los Angeles area is California's largest population center, it was expected that large hospitals (over 500 beds) would be over-represented in the surveyed study area. This expectation was confirmed by the calculation that although the inventory area contains 12% of the state's hospitals, these represent 19% of the acute care hospital beds in California. To reduce this bias, the emission factors were determined for three sizes of hospitals: under 200 beds, 200 to 499 beds, and 500 beds and over. However, the amount of error introduced into the estimate by the biased sample can not be determined.

Analysis of variance for the emission factors indicates confidence limits of plus or minus 31% due to internal variability within categories and small sample size for some categories.

EXPOSURE EXTRAPOLATION

Because the average exposure estimated for the population in the grid includes people exposed to high concentrations due to emissions from Micro-Biotrol Inc., this estimate is not indicative of exposure experienced by people in the rest of the state. One approach to estimating statewide exposure would be to exclude all exposure due to industrial sources. No quantitative data exist to evaluate this approach. The following is a qualitative assessment of the factors affecting the validity of this approach to estimating statewide exposure.

Although the state's largest urban areas do have industrial sources, most urban areas have no industrial sources of ethylene oxide exposure. In most urban areas, the exposure resulting from hospital emissions will be the only source of exposure. Sources of uncertainty in the estimate of other urban community exposure derived by extrapolation from the South Coast modeling study include the following: 1) meteorological and topographic conditions vary around the state, and 2) the geographic distribution of hospitals varies among urban areas. Although the extent of error introduced by these sources of uncertainty is difficult to quantify, no reason was apparent to obviate the use of exposure from non-industrial sources in the South Coast to estimate statewide exposure.

For the purpose of estimating statewide population-weighted concentrations, however, it should be noted that 1) many rural areas have no ethylene oxide emission sources nearby, and 2) some smaller urban areas do have non-hospital (industrial) emission sources. Consideration of the first factor would imply that statewide population-weighted concentrations are somewhat lower, while the second factor would imply the opposite. Again, quantification is difficult.

APPENDIX H

EMISSIONS OF ETHYLENE OXIDE FROM MEDICAL/PHARMACEUTICAL PRODUCTS FACILITIES

EMISSIONS OF ETHYLENE OXIDE FROM MEDICAL/PHARMACEUTICAL PRODUCTS FACILITIES

The 1982 ARB survey included the following parameters pertaining to ethylene oxide (ETO) sterilizers: 1) the number of sterilizers, 2) the volume of the sterilizer unit, 3) the number of cycles used per week, 4) the kind of gas or gas mixture used for sterilizing in each unit, 5) the amount of gas or gas mixture used for each cycle, 6) the kind of ventilation system for the sterilizers and 7) the name of the ETO distributor. It is assumed that, without any emission control devices for the sterilizers, all the ETO used in the process will be emitted to the air.

Based on information collected by the survey, the ETO emissions were calculated as follows:

Annual ETO emissions = Amount of ETO used per cycle x number
of cycles used per week x 52 weeks

In cases where respondents did not provide information or provided incorrect information on the amount of gas or gas/mixture used, the annual ETO emissions were calculated based on an average value relating the mass of ETO used per cycle to the volume of the sterilizers. The average value is derived based on the assumptions that 1) the operating conditions for sterilization with 100 percent ETO are typical and similar, 2) the operating conditions for sterilization with 12% ETO/88% dichlorodifluoromethane are typical and similar, and 3) both the conditions mentioned above are under ideal gas conditions.

Given: 1) $PV = nR^*T$ where P = pressure
V = volume of the sterilizer
n = number of moles of ETO
R^* = universal gas constant
T = temperature

2) $n = m/M$ where m = mass of ETO (amount of ETO used per cycle)
M = molecular weight of ETO

Then: 1) $PV = mR^*T/M$
$= m(R^*/M)T$ where R^*/M = specific gas constant = R

2) $m = PV/RT$
$m = (P/RT)V$

The average value of the term (P/RT) was empirically calculated based on the reported data on the amount of ETO used per cycle and the volume available in completed survey responses. This average value of (P/RT) was then used to estimate the amount of ethylene oxide used per cycle for the companies which reported only the volume but not the amount of ETO (or incorrectly reported the amount of ETO used per cycle). An average value of 0.075 was used for cycles that used 100 percent ETO. An average value of 0.04 was used for cycles that used 12% ETO/88% dichlorodifluoromethane.